FORM PTO-1390 (REV. 9-2001) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY 'S DOCKET NUMBER: SMB-PT037 (PC 00 430 B US)

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/030805

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/06430	07/07/2000	13/07/1999

TITLE OF INVENTION: METHOD AND DEVICE FOR PRESERVING ANIMAL AND HUMAN PREPARATIONS AS WELL AS MICROORGANISMS AND FOR PROLONING THE VIABILITY OF ORGANS AND BODY PARTS TO BE TRANSPLANTED

APPLICANT(S) FOR DO/EO/US: Zimmermann et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [ ] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [X] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [X] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [X] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [X] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Unsigned
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [X] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [X] Other items or information:

PCT/EP00/06430 Cover Sheet; Drawings;
International Preliminary Examination Report with positive findings of novelty, inventive step and industrial applicability for claims 1-23; and
Application Data Sheet.

U.S. APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
10/030805	PCT/EP00/06430	SMB-PT037 (PC 00 430 B US

21. ☒ The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	23 - 20 =	3	x **$18.00**	$ 54	
Independent claims	1 - 3 =	0	x **$84.00**	$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$280.00**	$ -	
TOTAL OF ABOVE CALCULATIONS =				$ 944	
☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. +				$ 0	
SUBTOTAL =				$ 944	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$ -	
TOTAL NATIONAL FEE =				$ 944	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ -	
TOTAL FEES ENCLOSED =				$ 944	
				Amount to be refunded:	$
				charged:	$

a. ☒ A check in the amount of $ 944 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 22-0493 . A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Volpe and Koenig, P.C.
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SIGNATURE

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NAME

34,626
REGISTRATION NUMBER

10/030805
531 Rec'd PCT/PTO 11 JAN 2002

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the **PATENT APPLICATION** of:

Zimmermann et al.

PCT Int'l. Appln. No.: PCT/EP00/06430

U.S. Application No.: Not Yet Known

Confirmation No.: Not Yet Known

Filed: Not Yet Known

For: METHOD AND DEVICE FOR PRESERVING ANIMAL AND HUMAN PREPARATIONS AS WELL AS MICROORGANISMS FOR PROLONGING THE VIABILITY OF ORGANS AND BODY PARTS TO BE TRANSPLANTED

Group: Not Yet Known

Examiner: Not Yet Known

Our File: SMB-PT038 (PC 00 430 B US)

Date: January 11, 2002

10030805.011502

PRELIMINARY AMENDMENT

Box PCT
Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the present application as noted in detail below.

IN THE CLAIMS

Please amend the claims as follows:

3. (Amended) A method according to claim 1, characterised in that the material to be treated is pressurised with high pressure on the one hand and on the other hand with

a pressure reduced relative to the high one for different time spans and that the pressurising with high pressure lasts at least for approx. 1 minute per period and in particular lasts longer than the pressurising with low pressure.

4. (Amended) A method according to claim 1, characterised in that the pressure relief is carried out from high pressure to atmospheric pressure.

5. (Amended) A method according to claim 1, characterised in that the periodic pressurising for a portion of the material to be treated is carried out over a time span of a few seconds, preferably from three minutes up to twenty hours.

6. (Amended) A method according to claim 1, characterised in that the time span of the periodic pressurising is chosen depending from the allocated maximum pressure and/or the material to be treated.

7. (Amended) A method according to claim 1, characterised in that filtered and/or cooled atmospheric air is supplied to the vessel.

8. (Amended) A method according to claim 1, characterised in that the blood vessel system of a preparation formed by a part preparation or a complete body or an organ or body part is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like.

9. (Amended) A method according to claim 1, characterised in that the organ or body part to be transplanted is connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to an artificial blood circulation.

10. (Amended) A method according to claim 1, characterised in that after being preserved, when carrying out experiments, especially simulating surgical operations, the blood vessel system of a preparation, formed by a part preparation or a complete body preparation, is connected to a through-flushing by fluid, in particular to an artificial blood circulation and that for this purpose the preparation or the similar material to be treated with at least one large blood vessel is connected to a preferably pulsating fluid supply, in particular with at least one large artery and/or at least one vein.

11. (Amended) A method according to claim 8, characterised in that the blood circulations of the preparation or the like are filled with a blood substitute that has a colloid-osmotic pressure that is comparable with that of blood.

13. (Amended) A method according to claim 1, characterised in that the atmospheric air is compressed and then is supplied to the vessel (2) filtered and/or cooled.

14. (Amended) A method according to claim 1, characterised in that the atmospheric pressure is compressed, stored intermediately at a pressure of between approx. 10 bar and approx. 1000 bar and then supplied to the vessel (2), preferably filtered and/or cooled.

15. (Amended) A method according to claim 1, characterised in that the treatment of the material to be treated is carried out in a cooled ambient atmosphere approx. between -2°C and +5°C.

16. (Amended) A method according to claim 1, characterised in that the vessel (2) for the material to be treated is cooled preferably by a cooled ambient atmosphere and

that the time spans with a periodic pressure increase and a subsequent pressure decrease in the vessel (2) are so determined that at the end of each time span a specifiable temperature will prevail in the vessel (2).

17. (Amended) A device to preserve animal and human preparations as well as microorganisms or similar material to be treated and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby the device has at least one vessel that can be closed in an airtight manner to accommodate the material to be treated, with a gas supply line as well as a gas discharge line connected to said vessel, to carry out the method according to claim 1, characterised in that a compressor (6) is connected to the gas supply line (5) to supply ambient air to the vessel (2), that a discharge valve (12) is provided in the gas discharge line (11), that a pressure sensor (13) is provided to measure the internal pressure of the vessel and that the compressor (6), the discharge valve as well as the pressure sensor (13) are connected to a control device (14) for the purpose of a periodic supply and discharge of the air.

19. (Amended) A device according to claim 17, characterised in that as the source of the compressed air at least one high-pressure reservoir (17) is provided for an operating pressure of approx. 10 bar up to 1000 bar.

21. (Amended) A device according to claim 19, characterised in that the treatment vessel (2) is connected with a cooling equipment and is arranged preferably in a cooled ambient atmosphere, in particular in a cooling chamber (19).

23. (Amended) A device according to claim 19, characterised in that the high-pressure reservoir (17) is arranged in a cooled ambient atmosphere, in particular in a cooling chamber (17).

REMARKS

Claims 1-23 are currently pending in this application, as amended. By this amendment, Applicants have amended claims 3-11, 13-17, 19, 21 and 23 in order to cancel the improper multiple dependencies. Copies of the claims are attached showing the changes with underlining and brackets.

Prompt examination of the present application is respectfully requested.

Respectfully submitted,

Zimmermann et al.

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37 CFR §1.121(b)(1)(iii) CLAIM AMENDMENTS- MARKED UP VERSION

3. A method according to claim 1 [or 2], characterised in that the material to be treated is pressurised with high pressure on the one hand and on the other hand with a pressure reduced relative to the high one for different time spans and that the pressurising with high pressure lasts at least for approx. 1 minute per period and in particular lasts longer than the pressurising with low pressure.

4. (Amended) A method according to [any one of] claim[s] 1 [to 3], characterised in that the pressure relief is carried out from high pressure to atmospheric pressure.

5. (Amended) A method according to [any one of] claim[s] 1 [to 4], characterised in that the periodic pressurising for a portion of the material to be treated is carried out over a time span of a few seconds, preferably from three minutes up to twenty hours.

6. (Amended) A method according to [any one of] claim[s] 1 [to 5], characterised in that the time span of the periodic pressurising is chosen depending from the allocated maximum pressure and/or the material to be treated.

7. (Amended) A method according to [any one of] claim[s] 1 [to 6], characterised in that filtered and/or cooled atmospheric air is supplied to the vessel.

8. (Amended) A method according to [any one of] claim[s] 1 [to 7], characterised in that the blood vessel system of a preparation formed by a part preparation or a complete body or an organ or body part is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like.

9. (Amended) A method according to [any one of] claim[s] 1 [to 8], characterised in that the organ or body part to be transplanted is connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to an artificial blood circulation.

10. (Amended) A method according to [any one of] claim[s] 1 [to 8], characterised in that after being preserved, when carrying out experiments, especially simulating surgical operations, the blood vessel system of a preparation, formed by a part preparation or a complete body preparation, is connected to a through-flushing by fluid, in particular to an artificial blood circulation and that for this purpose the preparation or the similar material to be treated with at least one large blood vessel is connected to a preferably pulsating fluid supply, in particular with at least one large artery and/or at least one vein.

11. (Amended) A method according to claim 8 [or 10], characterised in that the blood circulations of the preparation or the like are filled with a blood substitute that has a colloid-osmotic pressure that is comparable with that of blood.

13. (Amended) A method according to [any one of] claim[s] 1 [to 12], characterised in that the atmospheric air is compressed and then is supplied to the vessel (2) filtered and/or cooled.

14. (Amended) A method according to [any one of] claim[s] 1 [to 12], characterised in that the atmospheric pressure is compressed, stored intermediately at a

pressure of between approx. 10 bar and approx. 1000 bar and then supplied to the vessel (2), preferably filtered and/or cooled.

15. (Amended) A method according to [any one of] claim[s] 1 [to 14], characterised in that the treatment of the material to be treated is carried out in a cooled ambient atmosphere approx. between -2°C and +5°C.

16. (Amended) A method according to [any one of] claim[s] 1 [to 15], characterised in that the vessel (2) for the material to be treated is cooled preferably by a cooled ambient atmosphere and that the time spans with a periodic pressure increase and a subsequent pressure decrease in the vessel (2) are so determined that at the end of each time span a specifiable temperature will prevail in the vessel (2).

17. (Amended) A device to preserve animal and human preparations as well as microorganisms or similar material to be treated and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby the device has at least one vessel that can be closed in an airtight manner to accommodate the material to be treated, with a gas supply line as well as a gas discharge line connected to said vessel, to

carry out the method according to [any one of] claim[s] 1 [to 16], characterised in that a compressor (6) is connected to the gas supply line (5) to supply ambient air to the vessel (2), that a discharge valve (12) is provided in the gas discharge line (11), that a pressure sensor (13) is provided to measure the internal pressure of the vessel and that the compressor (6), the discharge valve as well as the pressure sensor (13) are connected to a control device (14) for the purpose of a periodic supply and discharge of the air.

19. (Amended) A device according to [any one of] claim[s] 17 [to 18], characterised in that as the source of the compressed air at least one high-pressure reservoir (17) is provided for an operating pressure of approx. 10 bar up to 1000 bar.

21. (Amended) A device according to [any one of] claim[s] 19 [to 20], characterised in that the treatment vessel (2) is connected with a cooling equipment and is arranged preferably in a cooled ambient atmosphere, in particular in a cooling chamber (19).

23. (Amended) A device according to [any one of] claim[s] 19 [to 22], characterised in that the high-pressure reservoir (17) is arranged in a cooled ambient atmosphere, in particular in a cooling chamber (17).

VERIFICATION OF TRANSLATION

I, *Thomas Ermer*

of *Wordmaster Translations P/L, 19 High Road, Camberwell, 3124, Victoria, Australia*

am the translator of the document(s) attached and I state that the following is a true translation to the best of my knowledge and belief of

International patent application PCT/EP00/06430 (WO 01/03505 A1)

Dated: *11.12.2001*

Signature of translator: _____

NATIONAL ACCREDITATION AUTHORITY FOR TRANSLATORS AND INTERPRETERS
NAATI No. 11738
THOMAS ERMER
TRANSLATOR
GERMAN -> ENGLISH

Method and device for preserving animal and human preparations as well as microorganisms and for prolonging the viability of organs and body parts to be transplanted

The invention concerns a method and a device to preserve animal and human preparations as well as microorganisms or similar material to be treated, in particular for medical research and/or training and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby carbon dioxide is expelled from the cells of the material to be treated.

In medical training and research humans and experimental animals or individual body parts or organs are required. At the same time the problem is that these preparations should be available as fresh as possible, without injuries, in large numbers and independently from the time, i.e. on demand. At the same time the dead tissue should be as similar to the living tissue as possible to obtain results as close as possible to the practical. On this occasion the consistency of the tissue, its elasticity, colour and shape are paramount.

In techniques used so far the preparations have to be placed into formalin or something similar. However, in this case it is a disadvantage that the colour and consistency change considerably. In addition, formalin is a toxic material that chemically modifies the tissue. This will change the functional behaviour of the cell tissue fragments, resulting in considerable disadvantages as far as the purpose of the research is concerned. In addition, due to the toxicity a reuse is not possible, so that transplants of such preparations, treated with formalin, is out of the question. There is the further possibility to deep freeze the preparations. However, during the thawing out the natural decomposition is activated and accelerated, so that the preparations have to be used within hours.

A further possibility is to use fresh preparations. For this purpose the animal is slaughtered shortly before. This, however, necessitates a well organised and expensive effort, since the regulations regarding protection of animals specifies, for example, quarantine regulations, special disposals, permission by the ethical commission.

In the case of body part or organ transplants there is, inter alia, the problem of transport. Organs have to be transported sometimes over thousands of kilometres from the donor to the recipient. The danger in this case is that the natural decomposition could set in. To retard this, the organ is cooled and sometimes it is placed into a nutritive solution. Despite this the organ has to be used within hours before the cells are permanently damaged.

The use of oxygen for the purpose of reduction of the natural decomposing process is already known.

Research publications are also known, wherein hyperbaric oxygen is used under pressure to improve the healing of a wound.

Furthermore the transplanting of a rat's ear is known, whereby the hyperbaric oxygen was used under a pressure of 2 bar with the aim to improve the adhesion of the transplanted organ.

When a rat's liver was transplanted, it was treated with hyperbaric, 100% oxygen at 2.5 bar pressure over the atmospheric one before its removal so that to reduce ischemic damages (anaemia) during the renewed blood circulation of the organ.

Furthermore, the transplant of a rabbit's lung using EuroCollins solution (nutritive solution) and a 95% oxygen/5% CO_2 atmosphere at a pressure of 2 bar is known.

It is known from experiments, that in the case of rat cells, subjected to hyperbaric oxygen under a pressure of 2.8 bar for a longer period, damages have occurred.

Therefore the state-of-the-art in the medicine is the use of high-percentage (95% or higher) oxygen as well as pressurising.

For the oxygen supply either oxygen bottles or an oxygen concentrator is used. To purchase and practically operate either of them, not-inconsiderable expenses are required. When oxygen bottles are used, they have to be continuously exchanged, thus rendering the operation of the device elaborate. In addition, the

prescribed safety regulations have to be observed when handling and storing oxygen bottles.

Therefore it is a particular task to produce a method to preserve and treat preparations, with the aid of which preparations can be preserved even over a relatively long period of time, so that surgical exercises could be carried out on these within the prolonged preservation period under lifelike conditions. In addition, a prolonged viability should be provided for the organ or body part transplant.

The solution for this method according to the invention is in particular that the preparation or the similar material to be treated is subjected inside a vessel to atmospheric air that is increased periodically up to at least approx. 10 bar and subsequently, after a specifiable period of time that is adjusted to suit the material to be treated, is reduced, that after the decrease of the pressure air is supplied from the outside and the pressure is increased up to at least approx. 10 bar and that at least two pressure phases are provided for a treatment.

The use of atmospheric air, in conjunction with the periodic pressurising, considerably simplifies the treatment method since an elaborate supply of oxygen from oxygen bottles or the use of an oxygen concentrator becomes redundant. In addition, the treatment can be concluded after a considerably shorter time. This is the result of being charged by relatively high pressures which, according to an embodiment of the invention, can be 10 bar up to approx. 100 bar. This charging of the material to be treated by high pressure affects a faster diffusion of the oxygen of the air.

Experiments have shown that already two pressure phases with reliefs between them will sufficiently prolong the durability.

The treatment, using the method according to the invention, allows the post-decrease preservation of humans, animals and microorganisms or their parts. The decay commences usually within a few hours. The method according to the invention can delay this up to several weeks. At the same time the colour of the

tissue as well as its consistency, especially with regard to strength and elasticity, are retained, so that it can be used as a fresh preparation. Accordingly, preparations are available that are very lifelike and can be removed, for example, for surgical courses, from the preserving device. At the same time the consistency of the tissue is almost that of fresh tissue. This is demonstrated by physically testing the elasticity of the tissue.

Apart from the scientific advantages, the method also facilitates the organisation itself. Several preparations can be preserved and used when required and experiments can be carried out independently from the supply/slaughter of experimental animals. This results in a financial saving, at least when compared with experiments using fresh preparations.

The method can save in animal experimentations, since a multiple use and storage of individual preparations is possible.

The longer durability of pre-treated preparations can be also attributed to the fact that the development of certain groups of germs can be hindered by the oxygen gas. The oxygen contained in the atmospheric air, supplied under pressure, has a growth-hindering effect on the germ and possibly even a bactericidal effect. This bactericidal effect acts effectively against the accelerated decay processes. Moreover, oxidative changes are also prevented or at least reduced over a longer period of time, what can be noticed by a near-realistic colour of the flesh of the animal preparation.

In the case of animal and human preparations one could deal both with part preparations and complete body preparations.

By virtue of the method according to the invention in the case of body part or organ transplants now a prolonged period of time is available, within which after its removal the organ is brought to the place of transplant and used there, because the viability of the organs and body parts can be retained longer.

In a useful manner the material to be treated is pressurised with high pressure on the one hand and on the other hand with a pressure reduced relative to the high one for different time spans, while the pressurising with high pressure lasts at least for approx. 1 to 10 minutes per period and in particular lasts longer than the pressurising with low pressure. The duration of the pressurising, the maximum pressure used for this and the number of pressure periods can be adjusted to suit the respective preparation by varying one or several of these parameters.

The periodic pressurising of the material to be treated can be carried out over time spans of a few seconds, preferably of 3 minutes, up to 20 hours.

This extremely broad time span for a periodic compressed air treatment is the result of the broad field of application of the method according to the invention for very different preparations.

Accordingly, the time span of the periodic pressurising is chosen depending from the allocated maximum pressure and/or the material to be treated.

It is useful to supply filtered and/or cooled atmospheric air to the treatment vessel.

By supplying cooled air, the vessel for the preparations or the like can be practically placed anywhere, i.e. also outside of a cooling chamber. The supply of filtered air also contributes to this, since due to this the vessel can be placed practically anywhere.

By means of the preserving method according to the invention, the preparations (complete bodies or part preparations) treated with it are available for a relatively long period of time with a consistence corresponding almost to that of fresh preparations. To produce conditions as close as possible to real life during experimentations, the animal or human preparations, in addition to the consistency of fresh preparations achieved by preservation, an additional near-realistic measure could provide that after being preserved, when carrying out experiments, especially simulating surgical operations, the blood vessel system

of a preparation, formed by a part preparation or a complete body preparation, is connected to a through-flushing by fluid, in particular to an artificial blood circulation and that for this purpose the preparation or the similar material to be treated with at least one large blood vessel is connected to a preferably pulsating fluid supply, in particular with at least one large artery and/or at least one vein.

When simulating surgical operations on the preparations, this fluid supply to the blood vessels has the effect that in a realistic manner during the incision of the preparation it trickles from the smaller blood vessels whereas the fluid squirts from the large blood vessels. Thus a near-realistic blood and fluid flow is produced in the blood stream of the preparation.

The preservation method according to the invention can be particularly well used in combination with the method of artificial blood circulation, because in the case of this preservation method particularly the colour and consistency of the walls of the vessels of the large and especially of the small arteries and veins are retained even after longer preservation. Thus when a surgical operation is being simulated, unexpected bleedings may occur, for example by an erroneous incision, just like this is the case in actual operations. Thus the surgeon sees directly a realistic result of his activity.

This case can be simulated particularly life-like, so that the entire operation will have a life-like effect. Thus the surgeon can be presented with difficult situations also, so that he could securely master it also in practice.

It is useful if the blood vessel system of a preparation formed by a part preparation or a complete body or an organ or body part is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like.

This flushing through of the blood stream of the preparation or of the organ or of the body part can be carried out immediately after the slaughtering of the animal or after the removal of the organ or the like, so that to remove residual blood and

to prevent an adhesion of the vessels. By virtue of this the blood stream system remains passable for the subsequently supplied fluid, should it be necessary.

An organ or body part to be transplanted can be connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to a blood circulation.

It is advantageous if a blood substitute, having a colloid-osmotic pressure that is comparable with that of blood, is used. As a result of this the blood or similar fluid flowing in the blood stream of the preparation during its preparation can flow out under as realistic as possible conditions when the preparation is incised.

A preferred embodiment of the invention provides that the blood substitute or similar fluid is filled into the blood stream of the preparation by means of a pressure pump connected to at least one blood vessel.

With the aid of the above described treatment method according to the invention a preparation can also be prepared over a relatively long period of time under near-realistic conditions. Since the preparation can be kept fresh over a longer period of time, larger quantities of these preparations can be stored and made available practically any time.

The method according to the invention is particularly suited for research and training in the intervention radiology. It can be particularly well used for catheterisation, injections and microsurgical interventions using computer tomography control or magnetic resonance tomography control, since the life-like preservation of tissue structures and the possibility of an artificial blood circulation provides small vessels, realistic and life-like exposures (computer tomography images or magnetic resonance images).

There is also the possibility to intermediately store compressed atmospheric air at a pressure of between approx. 10 bar and approx. 1000 bar and then supply it to the vessel, preferably filtered and/or cooled.

By means of the intermediate storage the air, heated by the compression, can be intermediately stored and it can cool off during this time before being conveyed to the treatment vessel. By virtue of this the cooling effort is reduced because, inter alia, more time is available for this.

In a useful manner the vessel for the material to be treated is cooled preferably by a cooled ambient atmosphere, while the time spans with a periodic pressure increase and a subsequent pressure decrease in the vessel are so determined, that at the end of each time span a specifiable temperature will prevail in the vessel. By the incremental increase of the pressure and the partial decrease of the pressure, following each increase, in a desired manner the pressure level is brought closer to the intended end pressure on the one hand and due to the decrease of the pressure a reduction of the temperature, increased during the period of pressure increase, is achieved on the other. The decrease of the pressure takes place following the increase of the pressure before a perceivable temperature increase occurs in the treatment vessel. Each decrease of pressure can be, for example, approx. 1/3 of the previous pressure increase. Experiments have shown that at the same time the temperature in the treatment vessel can decrease even below the temperature of the cooling atmosphere surrounding the treatment vessel. The subsequent pressure increase preferably takes place again when an approximate temperature equalisation has been achieved, for example after 20 seconds.

The device provided for the carrying out of the method according to the invention has a vessel that can be closed in an airtight manner to accommodate the material to be treated, with a gas supply line and a gas discharge line connected to said vessel.

The device is characterised in that a compressor is connected to the gas supply line to supply ambient air to the vessel, that a discharge valve is provided in the gas discharge line, that a pressure sensor is provided to measure the internal pressure of the vessel and that the compressor, the discharge valve as well as the pressure sensor are connected to a control device for the purpose of a periodic supply and discharge of the air.

The device according to the invention has an altogether simple construction and is constructed from cost-effective, commercially available single components. The treatment of preparations, organs, body parts and the like can be carried out with this device by placing them into the pressure vessel and subsequently periodically charging them with air while the vessel is enclosed. The compressor, connected to the vessel to produce the compressed air, in conjunction with the discharge valve as well as with the pressure sensor can operate according to a operating program that can be set by the control device, so that a practically fully automated operation is possible.

The control device can comprise a program memory, in which the various treatment programs can be stored, whereby each material to be treated and/or the treatment time available are taken into consideration.

In a preferred manner in the air supply line, in particular after the compressor, a filter and/or a cooling equipment is provided. By including a filter and a cooling equipment the device represents a complete operating unit that can be installed practically anywhere.

A variation of the embodiment of the device according to the invention provides that as the source of the compressed air at least one high-pressure reservoir is provided for an operating pressure of approx. 10 bar up to 1000 bar.

The use of a high-pressure reservoir makes it possible to operate the device according to the invention from one or several of such reservoirs, while this can be carried out also removed from a filling station with a compressor.

However, on the other hand it is possible to connect the high-pressure reservoir to the compressor or make it connectable and to connect its delivery end, via the air pressure valve, to the treatment vessel. In this case the high-pressure reservoir (or several of them) acts as an intermediate vessel. Accordingly, the compressor needs to be operated only for the filling operation and, unlike the case for a compressor directly connected to the treatment vessel, needs not be continuously operated over the entire duration of the treatment.

In a useful manner the treatment vessel is connected with a cooling equipment and arranged preferably in a cooled ambient atmosphere, in particular in a cooling chamber. Accordingly, the material to be treated, situated in the treatment vessel, can be cooled to the respective desired temperature and kept at this temperature, e.g. at approx. 4°C. In addition, the increase in temperature, caused by a pressure increase, is compensated for by the cooling.

The invention is explained with its essential details in the following based on the drawings. They show in:

Fig.1 - a schematic illustration of a device for the treatment of animal and human preparations, organs and body parts,

Fig.2 - a schematic illustration of a device according to the invention with high-pressure reservoirs as intermediate vessels,

Fig.3 - an illustration approximately corresponding to that of Fig.2, but with a cooling equipment between the high-pressure reservoirs and the vessel for the material to be treated,

Fig.4 - a schematic illustration of a device according to the invention, wherein a compressor is connected to a filling station for high-pressure reservoirs and wherein several treatment units, each with a vessel for the material to be treated, are positioned spatially separated from one another, and

Figs.5-7 - diagrams showing the progress of pressure and temperature inside a treatment vessel during the filling process, the treatment process and the ventilation process.

Fig.1 shows the essential functional groups of the device 1 according to the invention. It has a vessel 2 that can be closed in an airtight manner, into which the material 3 to be treated, indicated by dotted line, can be filled. In the case of material to be treated one deals in particular with animal and human preparations, organs or body parts.

The vessel 2, which can have any external shape, has a door 4, through which the interior of the vessel 2 can be accessed and by means of which the vessel can be closed in an airtight manner even after charging it with the material 3 to be treated.

An air supply line 5 is connected to the vessel 2, said line being connected to at least one compressor 6. Preferably a cooling unit 7 is positioned in the air supply line 5, the cooling unit provided particularly between the compressor 6 and the vessel 2. The air drawn in by the compressor 6 via a suction line 8 is preferably first conveyed through an air filter 9.

In the air supply line 5 there is an air pressure valve 10, in particular immediately before the vessel 2.

Furthermore, an air discharge line 11 is connected to the vessel 2 in which line a discharge valve 12 is provided.

A pressure sensor 13 serves the purpose of measuring the air pressure prevailing in the vessel 2 and the temperature in the vessel can be measured with a temperature sensor 16.

The valves 10 and 12, the pressure sensor 13 and the temperature sensor 16 as well as the compressor 6 and the cooling unit 7 are connected to a control device 14, by means of which the treatment process according to the invention is automatically controlled. A particular operating program for the progress can be specified particularly via an operating field 15. By virtue of this it is possible to suit the various materials to be treated and other specifications.

After charging the vessel 2 with the material 3 to be treated and after closing the door 4 and the air discharge line 11 with the aid of the discharge valve 12 in an airtight manner, the compressor 6 is switched on via the control device 14, so that in the case illustrated air, cooled with the aid of the cooling unit 7, is conveyed via the air supply line 5 into the interior of the vessel. On this occasion the internal pressure of the vessel is built up to at least 10 bar.

When the pre-set pressure is reached, it is sensed by the pressure sensor 13 and the compressor 6 is switched off via the control device 14. In this high-pressure phase the air supply line 5 is closed with the aid of the air pressure valve 10.

After a period of time, that can also be set, the discharge valve 12 is opened by the control device 14, until the air pressure in the interior of the vessel 2 is reduced to a specifiable value that can be detected by the pressure sensor 13. This pressure, reduced in comparison with the prior prevailing high pressure, may be between atmospheric pressure and the prior prevailing high pressure, however, its reduction up to atmospheric pressure is preferred. The discharge valve 12 is subsequently closed again, the air pressure valve 10 is opened and compressed air is conveyed again by the compressor 6, until a specified pressure is reached in the vessel 2, that is again at least 10 bar. The number of periodic pressurising with reliefs of the pressure in between, can be varied depending on the material to be treated.

With the aid of the temperature sensor 16 the cooled compressed air, conveyed via the cooling unit 7, can be kept in a specified temperature range.

The temperature is preferably kept in a region around 0°C, because at this temperature a particularly good exchange of carbon dioxide and oxygen takes place inside of the material to be treated. In addition, the bacterial decomposition is minimised at this temperature.

Fig.2 shows a constructive variation of the device 1a according to the invention, wherein high-pressure reservoirs 17 are provided between the compressor 6 and the treatment vessel 2. In the embodiment two of these high-pressure reservoirs 17 are illustrated, while the number of the reservoirs may vary depending on the requirements and site conditions. Instead of several small reservoirs a corresponding larger one could be employed.

With the aid of the compressor the high-pressure reservoirs 17 are filled with compressed air, while the filling pressure may be in the range of, for example,

50-1000 bar. The filling pressure is usually approx. 300 bar, because commercially available reservoirs can be used for these pressures.

The high-pressure reservoir(s) 17 is (are) connected to the vessel 2 via a compressed air supply line 18 and the air pressure valve 10 located on the inlet side of the treatment vessel 2.

In the case of reservoirs 17 acting as intermediate vessels for the compressed air a pressure-reducing valve (not illustrated) may be provided, so that compressed air at a constant pressure that is independent, to a great extent, from the internal pressure of the reservoir can be supplied to the vessel 2via the compressed air supply line 18.

In the embodiment shown in Fig.2 the treatment container 2 is situated inside of a cooling chamber 19 to enable to keep the internal temperature of the vessel 2, for example, at approx. 4°C.

The use of high-pressure reservoirs 17 has, inter alia, that advantage that the compressor has to be operated only to fill the reservoir 17 and it does not operate while the pressure in these reservoirs is adequate.

When device 1a is started up, atmospheric pressure prevails first in the treatment vessel 2 and the material 3 to be treated is placed in these vessels 2. At this time the temperature of the ambient atmosphere within the vessel 2 is 4°C or less. When the discharge valve 12 is closed, the filling process commences, whereby the inside pressure of the vessel 2 is increased periodically with increase and decrease phases up to a specified end pressure, e.g. 20 bar.

Fig.5 is a diagram, showing the progression of the pressure inside of the vessel 2 during the filling process on the one hand, and on the other, in dotted line, the progress of the temperature of the internal atmosphere of the vessel. In this embodiment the pressure increases from the atmospheric one up to 15 bar and the temperature moves between approx. 5°C and 0°C.

Beginning with the atmospheric pressure in the vessel 2, first of all the pressure is increased in a first period, whereby the pressure increase can be 10 bar. This pressure increase also brings about an increase of the temperature in the interior of the vessel, which, however, is compensated by a subsequent decrease of the pressure by approx. 1/3 to 1/2 of the previous pressure increase, together with the cooling of the vessel 2. If the level of temperature after the decrease of the pressure and a following time span is within a permissible range, the next pressure increase takes place with a subsequent partial decrease of the pressure, in each case while observing the temperature of the vessel. Experiments have shown that despite the increased overall pressure by decreasing the pressure short-term temperatures may occur below the temperature specified for the cooling.

The periods with pressure increase and pressure decrease are repeated until the required pressure level of, for example, 15 bar, is reached. In practice this could occur after 5-10 minutes.

This operational state remains over the treatment period of the material 3 to be treated. From the diagram according to Fig.6 it can be seen that the pressure is varied periodically, whereas the temperature is kept constant at approx. 0°C.

During the treatment period a partial air exchange can be carried out, whereby some air is discharged and subsequently compressed air is supplied. This limited air exchange can be carried out at short time intervals, while at somewhat longer time intervals, for example on every hour, the air exchange can be to a greater extent. At the same time a partial, or perhaps even a complete air exchange is possible in the treatment vessel.

After the treatment period, after the removal of the material 3 to be treated from the vessel 2, the pressure is reduced, while this may last, for example, half an hour. A relatively slow reduction of the pressure takes place, so that a too quick a temperature reduction will be avoided by virtue of the pressure reduction.

Fig.7 shows the ventilation process, wherein the pressure is reduced over a period of approximately half an hour from approx. 15 bar to atmospheric pressure.

Fig.3 shows a further version of the device 1b according to the invention, wherein the treatment vessel 2 is not situated in a cooling unit, as is the case in Fig.2. For this reason a cooling equipment 7a is connected downstream to the reservoirs 17, so that cooled air could be supplied to the vessel 2 to achieve the desired temperature in the vessel.

In the case of the embodiment according to Fig.4 a compressor 6 with a filling station 20 is allocated to several treatment units 21, each having a vessel 2, an air pressure valve 10, a discharge valve 12 as well as a control device 14. The treatment units 21 can be arranged spatially separated from the compressor 6. To each treatment unit 21 at least one mobile high-pressure reservoir 17 can be connected. This high-pressure reservoir can be filled at the central filling station 20, to which the compressor 6 is connected, and then connected to the respective treatment unit. Thus only one single filling station with compressor is required, via which several treatment units 21 can be supplied.

Claims

1. A method to preserve animal and human preparations as well as microorganisms or similar material to be treated, in particular for medical research and/or training and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby carbon dioxide is expelled from the cells of the material to be treated, characterised in that the material to be treated is subjected inside a vessel to atmospheric air that is increased periodically up to at least approx. 10 bar and subsequently, after a specifiable period of time that is adjusted to suit the material to be treated, is reduced, that after the decrease of the pressure air is supplied from the outside and the pressure is increased up to at least approx. 10 bar and that at least two pressure phases are provided for a treatment.

2. A method according to claim 1, characterised in that the periodic treatment with alternating pressurising of the material to be treated is carried out with a maximum pressure in the range of approx. 10 bar up to approx. 100 bar.

3. A method according to claim 1 or 2, characterised in that the material to be treated is pressurised with high pressure on the one hand and on the other hand with a pressure reduced relative to the high one for different time spans and that the pressurising with high pressure lasts at least for approx. 1 minute per period and in particular lasts longer than the pressurising with low pressure.

4. A method according to any one of claims 1 to 3, characterised in that the pressure relief is carried out from high pressure to atmospheric pressure.

5. A method according to any one of claims 1 to 4, characterised in that the periodic pressurising for a portion of the material to be treated is carried out over a time span of a few seconds, preferably from three minutes up to twenty hours.

6. A method according to any one of claims 1 to 5, characterised in that the time span of the periodic pressurising is chosen depending from the allocated maximum pressure and/or the material to be treated.

7. A method according to any one of claims 1 to 6, characterised in that filtered and/or cooled atmospheric air is supplied to the vessel.

8. A method according to any one of claims 1 to 7, characterised in that the blood vessel system of a preparation formed by a part preparation or a complete body or an organ or body part is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like.

9. A method according to any one of claims 1 to 8, characterised in that the organ or body part to be transplanted is connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to an artificial blood circulation.

10. A method according to any one of claims 1 to 8, characterised in that after being preserved, when carrying out experiments, especially simulating surgical operations, the blood vessel system of a preparation, formed by a part preparation or a complete body preparation, is connected to a through-flushing by fluid, in particular to an artificial blood circulation and that for this purpose the preparation or the similar material to be treated with at least one large blood vessel is connected to a preferably pulsating fluid supply, in particular with at least one large artery and/or at least one vein.

11. A method according to claim 8 or 10, characterised in that the blood circulations of the preparation or the like are filled with a blood substitute that has a colloid-osmotic pressure that is comparable with that of blood.

12. A method according to claim 11, characterised in that the blood substitute or similar fluid is filled into the blood stream of the preparation by means of a pressure pump connected to at least one blood vessel.

13. A method according to any one of claims 1 to 12, characterised in that the atmospheric air is compressed and then is supplied to the vessel (2) filtered and/or cooled.

14. A method according to any one of claims 1 to 12, characterised in that the atmospheric pressure is compressed, stored intermediately at a pressure of between approx. 10 bar and approx. 1000 bar and then supplied to the vessel (2), preferably filtered and/or cooled.

15. A method according to any one of claims 1 to 14, characterised in that the treatment of the material to be treated is carried out in a cooled ambient atmosphere approx. between -2°C and +5°C.

16. A method according to any one of claims 1 to 15, characterised in that the vessel (2) for the material to be treated is cooled preferably by a cooled ambient atmosphere and that the time spans with a periodic pressure increase and a subsequent pressure decrease in the vessel (2) are so determined that at the end of each time span a specifiable temperature will prevail in the vessel (2).

17. A device to preserve animal and human preparations as well as microorganisms or similar material to be treated and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby the device has at least one vessel that can be closed in an airtight manner to accommodate the material to be treated, with a gas supply line as well as a gas discharge line connected to said vessel, to carry out the method according to any one of claims 1 to 16, characterised in that a compressor (6) is connected to the gas supply line (5) to supply ambient air to the vessel (2), that a discharge valve (12) is provided in the gas discharge line (11), that a pressure sensor (13) is provided to measure the internal pressure of the vessel and that the compressor (6), the discharge valve as well as the pressure sensor (13) are connected to a control device (14) for the purpose of a periodic supply and discharge of the air.

18. A device according to claim 17, characterised in that in the gas or air supply line (5), in particular after the compressor (6), a filter (9) and/or a cooling equipment (7) is provided.

19. A device according to any one of claims 17 to 18, characterised in that as the source of the compressed air at least one high-pressure reservoir (17) is provided for an operating pressure of approx. 10 bar up to 1000 bar.

20. A device according to claim 19, characterised in that the high-pressure reservoir (17) is connected or can be connected to the compressor (6) and on the other hand it is connected to the treatment vessel (2) via air pressure valve (10).

21. A device according to any one of claims 19 to 20, characterised in that the treatment vessel (2) is connected with a cooling equipment and is arranged preferably in a cooled ambient atmosphere, in particular in a cooling chamber (19).

22. A device according to claim 21, characterised in that the treatment vessel (2) is provided with a cooling jacket as a cooling equipment.

23. A device according to any one of claims 19 to 22, characterised in that the high-pressure reservoir (17) is arranged in a cooled ambient atmosphere, in particular in a cooling chamber (17).

Abstract

A device to preserve animal and human preparations as well as microorganisms or similar material (3) to be treated, in particular for medical research and/or training. In addition to prolong the viability of organs and body parts to be transplanted which serve as material to be treated (3). For both fields of application carbon dioxide is expelled from the cells of the material to be treated.

The device has a vessel (2) that can be closed in an airtight manner to accommodate the material to be treated, to which a gas supply line (5) and a gas discharge line (11) are connected. A compressor (6) is connected to the gas supply line (5) to supply ambient air to the vessel (2) and the compressed air can be discharged from the vessel (2) via a discharge valve (12) in the gas discharge line (11).

The material (3) to be treated is exposed inside the vessel (2) to atmospheric air with periodically increasing pressure up to at least approx. 10 bar and subsequently, after a specifiable period of time, to a reduced pressure. After reducing the pressure, air from the outside is supplied by the compressor (6) and the pressure is increased again up to at least approx. 10 bar. At least two pressure phases are provided for a treatment. The treatment method is automatically controlled by means of a control device (14).

(Fig.1)

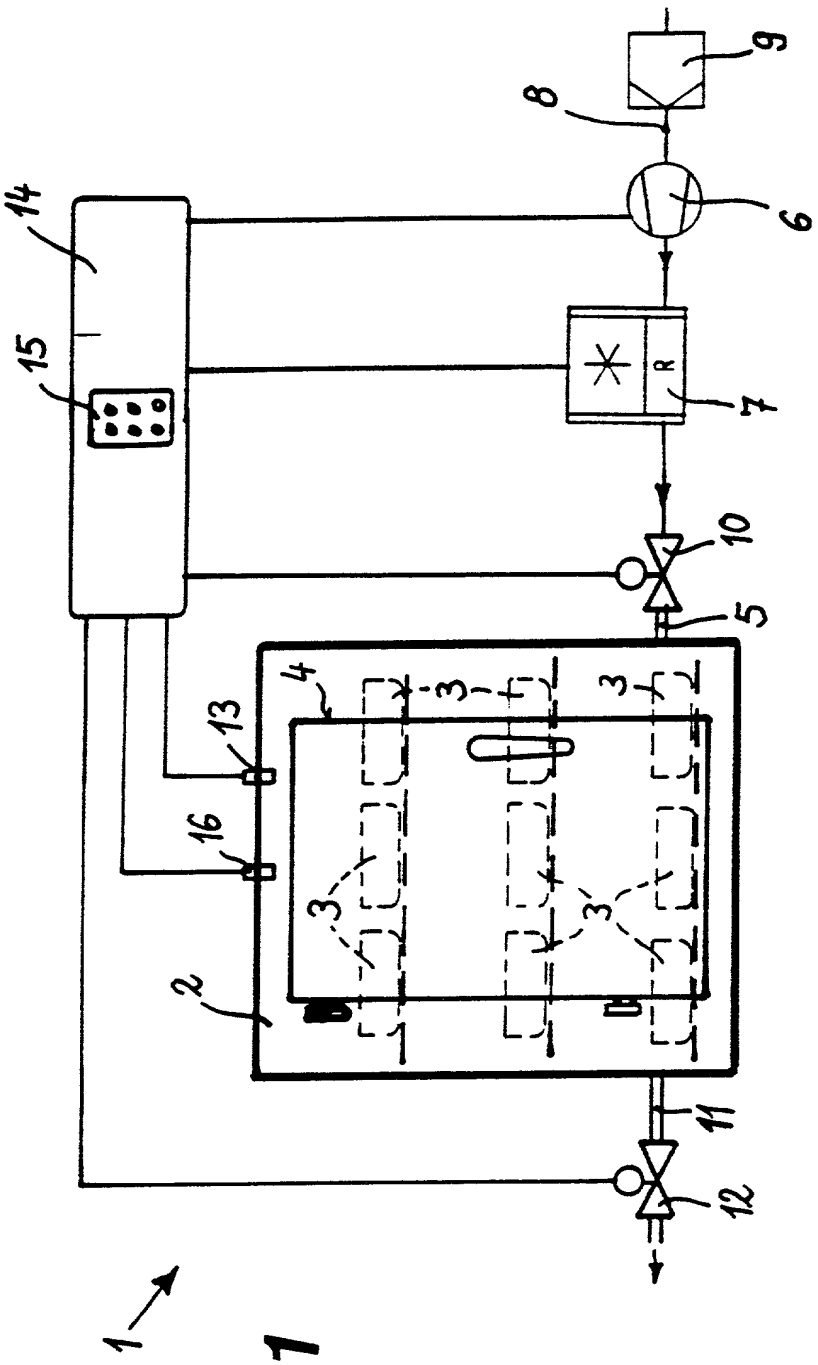


Fig.1

Fig.2

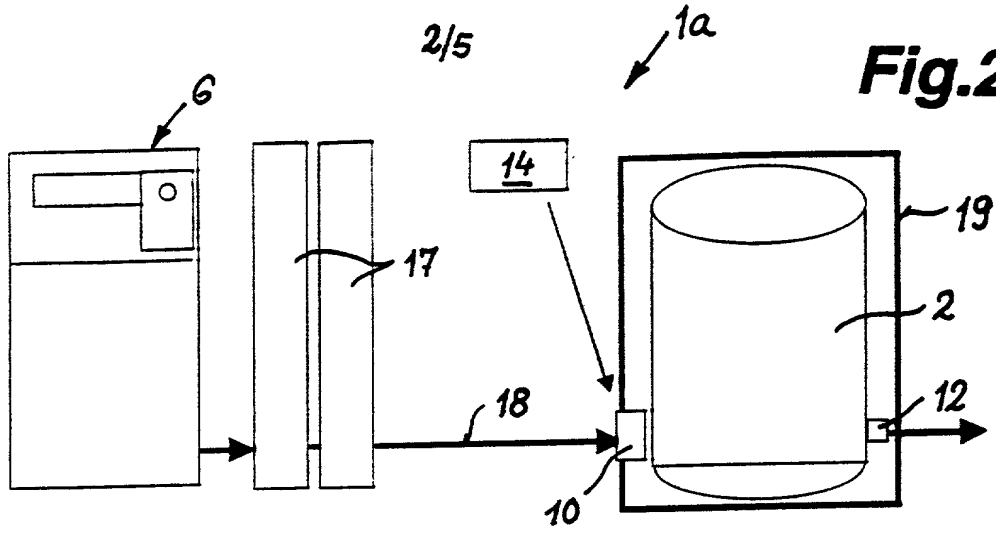


Fig.3

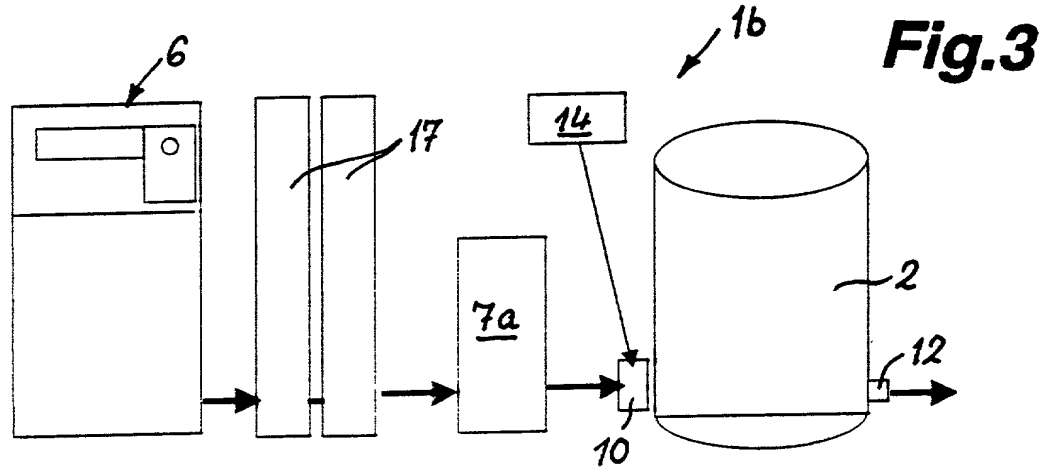
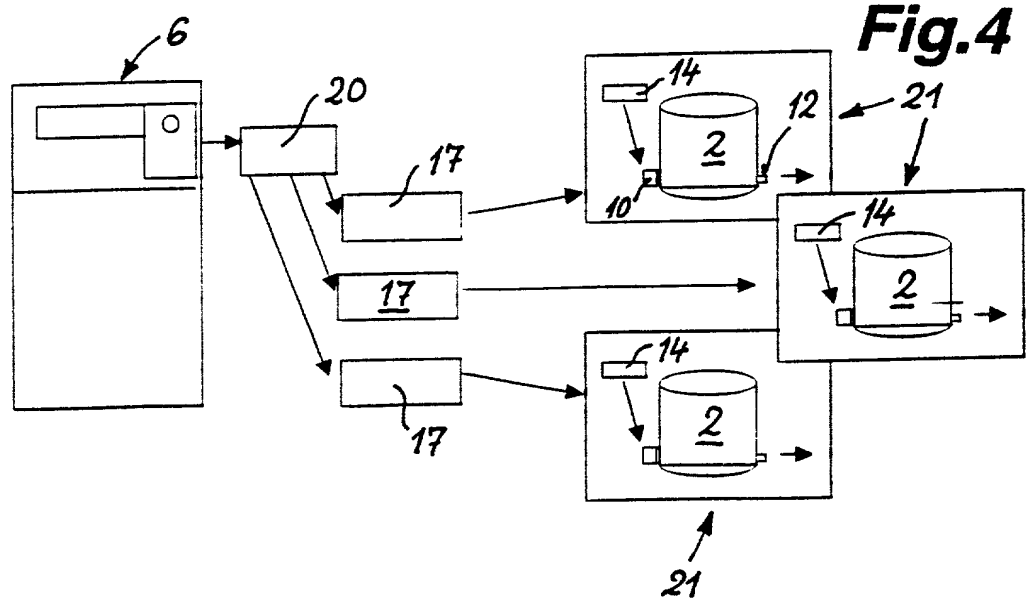


Fig.4



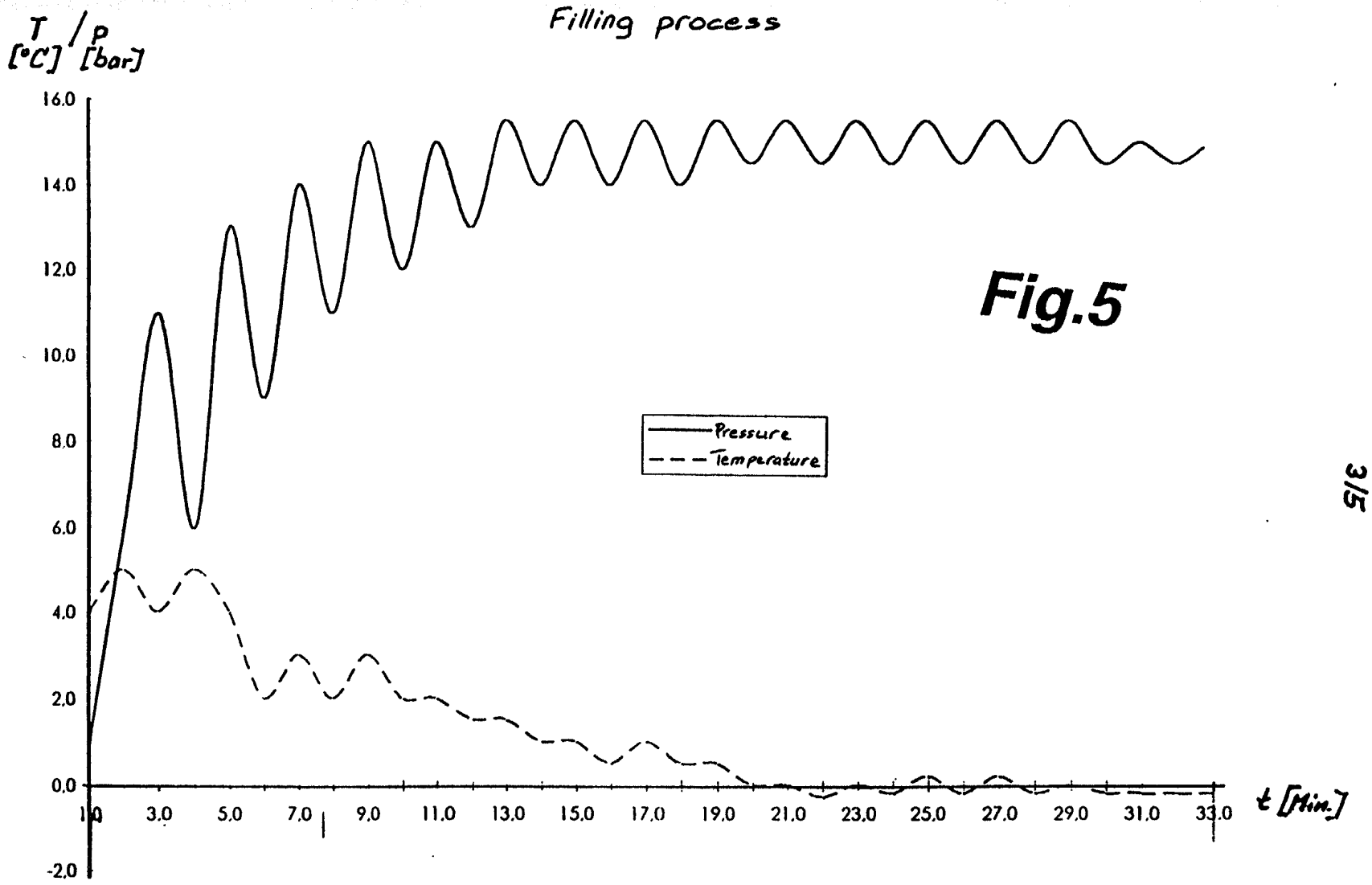


Fig.5

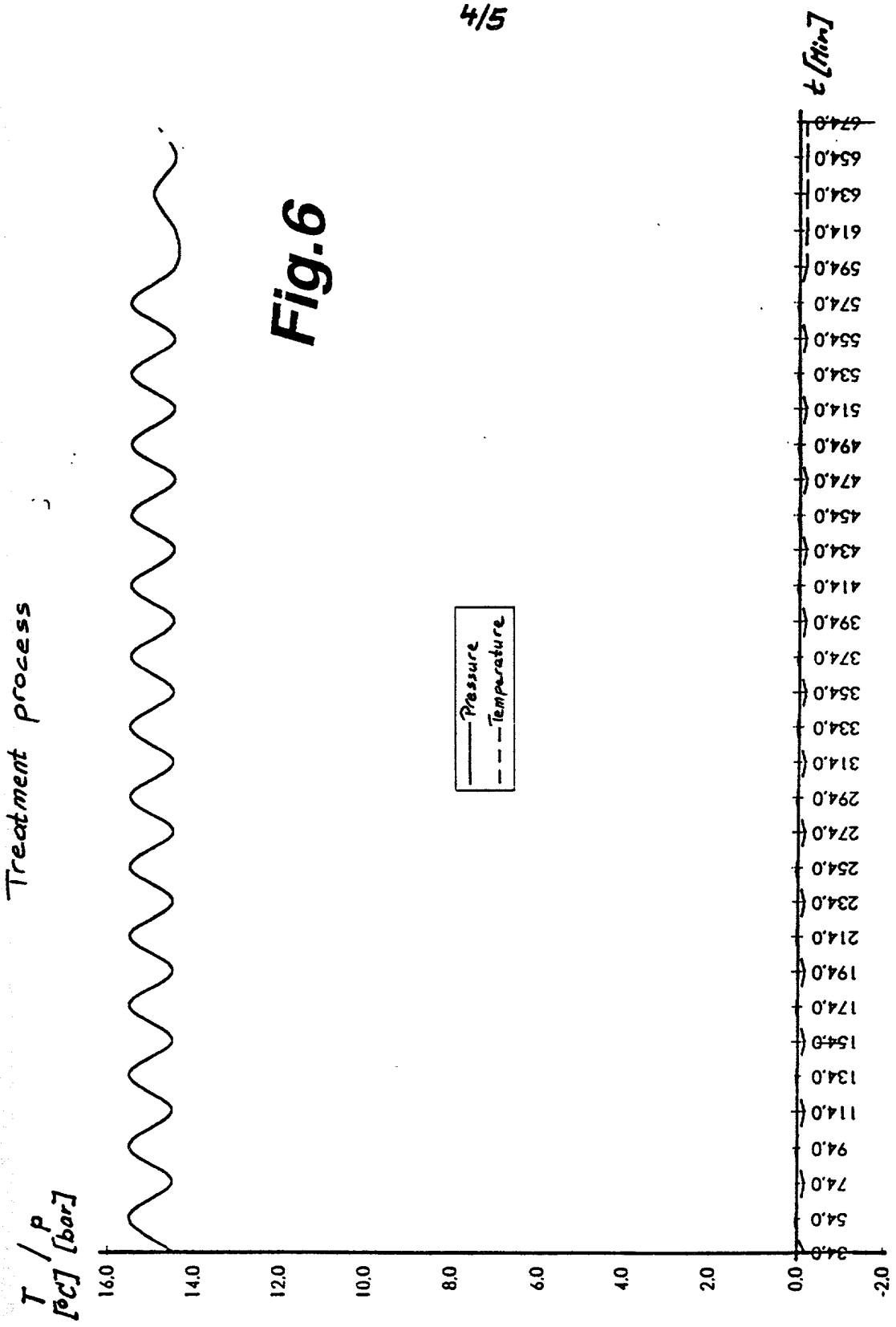
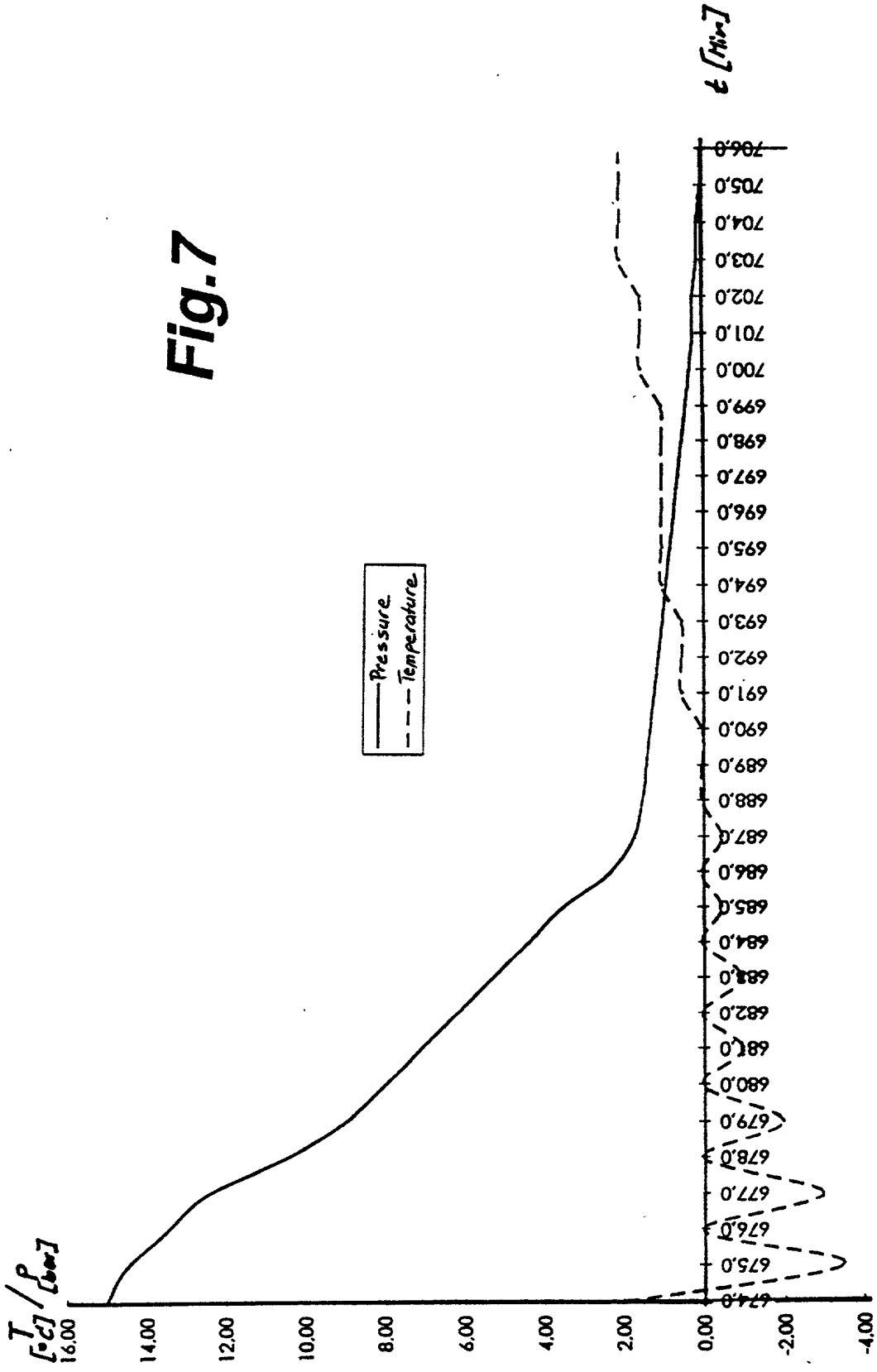


Fig.6

Fig.7



VERIFICATION OF TRANSLATION

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am the translator of the document(s) attached and I state that the following is a true translation to the best of my knowledge and belief of

International patent application PCT/EP00/06430 (WO 01/03505 A1)

Dated: *11.12.2001*

Signature of translator: ____________________

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TRANSLATOR
GERMAN -> ENGLISH

Method and device for preserving animal and human preparations as well as microorganisms and for prolonging the viability of organs and body parts to be transplanted

The invention concerns a method and a device to preserve animal and human preparations as well as microorganisms or similar material to be treated, in particular for medical research and/or training and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby carbon dioxide is expelled from the cells of the material to be treated.

In medical training and research humans and experimental animals or individual body parts or organs are required. At the same time the problem is that these preparations should be available as fresh as possible, without injuries, in large numbers and independently from the time, i.e. on demand. At the same time the dead tissue should be as similar to the living tissue as possible to obtain results as close as possible to the practical. On this occasion the consistency of the tissue, its elasticity, colour and shape are paramount.

In techniques used so far the preparations have to be placed into formalin or something similar. However, in this case it is a disadvantage that the colour and consistency change considerably. In addition, formalin is a toxic material that chemically modifies the tissue. This will change the functional behaviour of the cell tissue fragments, resulting in considerable disadvantages as far as the purpose of the research is concerned. In addition, due to the toxicity a reuse is not possible, so that transplants of such preparations, treated with formalin, is out of the question. There is the further possibility to deep freeze the preparations. However, during the thawing out the natural decomposition is activated and accelerated, so that the preparations have to be used within hours.

A further possibility is to use fresh preparations. For this purpose the animal is slaughtered shortly before. This, however, necessitates a well organised and expensive effort, since the regulations regarding protection of animals specifies, for example, quarantine regulations, special disposals, permission by the ethical commission.

In the case of body part or organ transplants there is, inter alia, the problem of transport. Organs have to be transported sometimes over thousands of kilometres from the donor to the recipient. The danger in this case is that the natural decomposition could set in. To retard this, the organ is cooled and sometimes it is placed into a nutritive solution. Despite this the organ has to be used within hours before the cells are permanently damaged.

The use of oxygen for the purpose of reduction of the natural decomposing process is already known.

Research publications are also known, wherein hyperbaric oxygen is used under pressure to improve the healing of a wound.

Furthermore the transplanting of a rat's ear is known, whereby the hyperbaric oxygen was used under a pressure of 2 bar with the aim to improve the adhesion of the transplanted organ.

When a rat's liver was transplanted, it was treated with hyperbaric, 100% oxygen at 2.5 bar pressure over the atmospheric one before its removal so that to reduce ischemic damages (anaemia) during the renewed blood circulation of the organ.

Furthermore, the transplant of a rabbit's lung using EuroCollins solution (nutritive solution) and a 95% oxygen/5% CO_2 atmosphere at a pressure of 2 bar is known.

It is known from experiments, that in the case of rat cells, subjected to hyperbaric oxygen under a pressure of 2.8 bar for a longer period, damages have occurred.

Therefore the state-of-the-art in the medicine is the use of high-percentage (95% or higher) oxygen as well as pressurising.

For the oxygen supply either oxygen bottles or an oxygen concentrator is used. To purchase and practically operate either of them, not-inconsiderable expenses are required. When oxygen bottles are used, they have to be continuously exchanged, thus rendering the operation of the device elaborate. In addition, the

prescribed safety regulations have to be observed when handling and storing oxygen bottles.

Therefore it is a particular task to produce a method to preserve and treat preparations, with the aid of which preparations can be preserved even over a relatively long period of time, so that surgical exercises could be carried out on these within the prolonged preservation period under lifelike conditions. In addition, a prolonged viability should be provided for the organ or body part transplant.

The solution for this method according to the invention is in particular that the preparation or the similar material to be treated is subjected inside a vessel to atmospheric air that is increased periodically up to at least approx. 10 bar and subsequently, after a specifiable period of time that is adjusted to suit the material to be treated, is reduced, that after the decrease of the pressure air is supplied from the outside and the pressure is increased up to at least approx. 10 bar and that at least two pressure phases are provided for a treatment.

The use of atmospheric air, in conjunction with the periodic pressurising, considerably simplifies the treatment method since an elaborate supply of oxygen from oxygen bottles or the use of an oxygen concentrator becomes redundant. In addition, the treatment can be concluded after a considerably shorter time. This is the result of being charged by relatively high pressures which, according to an embodiment of the invention, can be 10 bar up to approx. 100 bar. This charging of the material to be treated by high pressure affects a faster diffusion of the oxygen of the air.

Experiments have shown that already two pressure phases with reliefs between them will sufficiently prolong the durability.

The treatment, using the method according to the invention, allows the post-decrease preservation of humans, animals and microorganisms or their parts. The decay commences usually within a few hours. The method according to the invention can delay this up to several weeks. At the same time the colour of the

tissue as well as its consistency, especially with regard to strength and elasticity, are retained, so that it can be used as a fresh preparation. Accordingly, preparations are available that are very lifelike and can be removed, for example, for surgical courses, from the preserving device. At the same time the consistency of the tissue is almost that of fresh tissue. This is demonstrated by physically testing the elasticity of the tissue.

Apart from the scientific advantages, the method also facilitates the organisation itself. Several preparations can be preserved and used when required and experiments can be carried out independently from the supply/slaughter of experimental animals. This results in a financial saving, at least when compared with experiments using fresh preparations.

The method can save in animal experimentations, since a multiple use and storage of individual preparations is possible.

The longer durability of pre-treated preparations can be also attributed to the fact that the development of certain groups of germs can be hindered by the oxygen gas. The oxygen contained in the atmospheric air, supplied under pressure, has a growth-hindering effect on the germ and possibly even a bactericidal effect. This bactericidal effect acts effectively against the accelerated decay processes. Moreover, oxidative changes are also prevented or at least reduced over a longer period of time, what can be noticed by a near-realistic colour of the flesh of the animal preparation.

In the case of animal and human preparations one could deal both with part preparations and complete body preparations.

By virtue of the method according to the invention in the case of body part or organ transplants now a prolonged period of time is available, within which after its removal the organ is brought to the place of transplant and used there, because the viability of the organs and body parts can be retained longer.

In a useful manner the material to be treated is pressurised with high pressure on the one hand and on the other hand with a pressure reduced relative to the high one for different time spans, while the pressurising with high pressure lasts at least for approx. 1 to 10 minutes per period and in particular lasts longer than the pressurising with low pressure. The duration of the pressurising, the maximum pressure used for this and the number of pressure periods can be adjusted to suit the respective preparation by varying one or several of these parameters.

The periodic pressurising of the material to be treated can be carried out over time spans of a few seconds, preferably of 3 minutes, up to 20 hours.

This extremely broad time span for a periodic compressed air treatment is the result of the broad field of application of the method according to the invention for very different preparations.

Accordingly, the time span of the periodic pressurising is chosen depending from the allocated maximum pressure and/or the material to be treated.

It is useful to supply filtered and/or cooled atmospheric air to the treatment vessel.

By supplying cooled air, the vessel for the preparations or the like can be practically placed anywhere, i.e. also outside of a cooling chamber. The supply of filtered air also contributes to this, since due to this the vessel can be placed practically anywhere.

By means of the preserving method according to the invention, the preparations (complete bodies or part preparations) treated with it are available for a relatively long period of time with a consistence corresponding almost to that of fresh preparations. To produce conditions as close as possible to real life during experimentations, the animal or human preparations, in addition to the consistency of fresh preparations achieved by preservation, an additional near-realistic measure could provide that after being preserved, when carrying out experiments, especially simulating surgical operations, the blood vessel system

of a preparation, formed by a part preparation or a complete body preparation, is connected to a through-flushing by fluid, in particular to an artificial blood circulation and that for this purpose the preparation or the similar material to be treated with at least one large blood vessel is connected to a preferably pulsating fluid supply, in particular with at least one large artery and/or at least one vein.

When simulating surgical operations on the preparations, this fluid supply to the blood vessels has the effect that in a realistic manner during the incision of the preparation it trickles from the smaller blood vessels whereas the fluid squirts from the large blood vessels. Thus a near-realistic blood and fluid flow is produced in the blood stream of the preparation.

The preservation method according to the invention can be particularly well used in combination with the method of artificial blood circulation, because in the case of this preservation method particularly the colour and consistency of the walls of the vessels of the large and especially of the small arteries and veins are retained even after longer preservation. Thus when a surgical operation is being simulated, unexpected bleedings may occur, for example by an erroneous incision, just like this is the case in actual operations. Thus the surgeon sees directly a realistic result of his activity.

This case can be simulated particularly life-like, so that the entire operation will have a life-like effect. Thus the surgeon can be presented with difficult situations also, so that he could securely master it also in practice.

It is useful if the blood vessel system of a preparation formed by a part preparation or a complete body or an organ or body part is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like.

This flushing through of the blood stream of the preparation or of the organ or of the body part can be carried out immediately after the slaughtering of the animal or after the removal of the organ or the like, so that to remove residual blood and

to prevent an adhesion of the vessels. By virtue of this the blood stream system remains passable for the subsequently supplied fluid, should it be necessary.

An organ or body part to be transplanted can be connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to a blood circulation.

It is advantageous if a blood substitute, having a colloid-osmotic pressure that is comparable with that of blood, is used. As a result of this the blood or similar fluid flowing in the blood stream of the preparation during its preparation can flow out under as realistic as possible conditions when the preparation is incised.

A preferred embodiment of the invention provides that the blood substitute or similar fluid is filled into the blood stream of the preparation by means of a pressure pump connected to at least one blood vessel.

With the aid of the above described treatment method according to the invention a preparation can also be prepared over a relatively long period of time under near-realistic conditions. Since the preparation can be kept fresh over a longer period of time, larger quantities of these preparations can be stored and made available practically any time.

The method according to the invention is particularly suited for research and training in the intervention radiology. It can be particularly well used for catheterisation, injections and microsurgical interventions using computer tomography control or magnetic resonance tomography control, since the life-like preservation of tissue structures and the possibility of an artificial blood circulation provides small vessels, realistic and life-like exposures (computer tomography images or magnetic resonance images).

There is also the possibility to intermediately store compressed atmospheric air at a pressure of between approx. 10 bar and approx. 1000 bar and then supply it to the vessel, preferably filtered and/or cooled.

By means of the intermediate storage the air, heated by the compression, can be intermediately stored and it can cool off during this time before being conveyed to the treatment vessel. By virtue of this the cooling effort is reduced because, inter alia, more time is available for this.

In a useful manner the vessel for the material to be treated is cooled preferably by a cooled ambient atmosphere, while the time spans with a periodic pressure increase and a subsequent pressure decrease in the vessel are so determined, that at the end of each time span a specifiable temperature will prevail in the vessel. By the incremental increase of the pressure and the partial decrease of the pressure, following each increase, in a desired manner the pressure level is brought closer to the intended end pressure on the one hand and due to the decrease of the pressure a reduction of the temperature, increased during the period of pressure increase, is achieved on the other. The decrease of the pressure takes place following the increase of the pressure before a perceivable temperature increase occurs in the treatment vessel. Each decrease of pressure can be, for example, approx. 1/3 of the previous pressure increase. Experiments have shown that at the same time the temperature in the treatment vessel can decrease even below the temperature of the cooling atmosphere surrounding the treatment vessel. The subsequent pressure increase preferably takes place again when an approximate temperature equalisation has been achieved, for example after 20 seconds.

The device provided for the carrying out of the method according to the invention has a vessel that can be closed in an airtight manner to accommodate the material to be treated, with a gas supply line and a gas discharge line connected to said vessel.

The device is characterised in that a compressor is connected to the gas supply line to supply ambient air to the vessel, that a discharge valve is provided in the gas discharge line, that a pressure sensor is provided to measure the internal pressure of the vessel and that the compressor, the discharge valve as well as the pressure sensor are connected to a control device for the purpose of a periodic supply and discharge of the air.

The device according to the invention has an altogether simple construction and is constructed from cost-effective, commercially available single components. The treatment of preparations, organs, body parts and the like can be carried out with this device by placing them into the pressure vessel and subsequently periodically charging them with air while the vessel is enclosed. The compressor, connected to the vessel to produce the compressed air, in conjunction with the discharge valve as well as with the pressure sensor can operate according to a operating program that can be set by the control device, so that a practically fully automated operation is possible.

The control device can comprise a program memory, in which the various treatment programs can be stored, whereby each material to be treated and/or the treatment time available are taken into consideration.

In a preferred manner in the air supply line, in particular after the compressor, a filter and/or a cooling equipment is provided. By including a filter and a cooling equipment the device represents a complete operating unit that can be installed practically anywhere.

A variation of the embodiment of the device according to the invention provides that as the source of the compressed air at least one high-pressure reservoir is provided for an operating pressure of approx. 10 bar up to 1000 bar.

The use of a high-pressure reservoir makes it possible to operate the device according to the invention from one or several of such reservoirs, while this can be carried out also removed from a filling station with a compressor.

However, on the other hand it is possible to connect the high-pressure reservoir to the compressor or make it connectable and to connect its delivery end, via the air pressure valve, to the treatment vessel. In this case the high-pressure reservoir (or several of them) acts as an intermediate vessel. Accordingly, the compressor needs to be operated only for the filling operation and, unlike the case for a compressor directly connected to the treatment vessel, needs not be continuously operated over the entire duration of the treatment.

In a useful manner the treatment vessel is connected with a cooling equipment and arranged preferably in a cooled ambient atmosphere, in particular in a cooling chamber. Accordingly, the material to be treated, situated in the treatment vessel, can be cooled to the respective desired temperature and kept at this temperature, e.g. at approx. 4°C. In addition, the increase in temperature, caused by a pressure increase, is compensated for by the cooling.

The invention is explained with its essential details in the following based on the drawings. They show in:

Fig.1 - a schematic illustration of a device for the treatment of animal and human preparations, organs and body parts,

Fig.2 - a schematic illustration of a device according to the invention with high-pressure reservoirs as intermediate vessels,

Fig.3 - an illustration approximately corresponding to that of Fig.2, but with a cooling equipment between the high-pressure reservoirs and the vessel for the material to be treated,

Fig.4 - a schematic illustration of a device according to the invention, wherein a compressor is connected to a filling station for high-pressure reservoirs and wherein several treatment units, each with a vessel for the material to be treated, are positioned spatially separated from one another, and

Figs.5-7 - diagrams showing the progress of pressure and temperature inside a treatment vessel during the filling process, the treatment process and the ventilation process.

Fig.1 shows the essential functional groups of the device 1 according to the invention. It has a vessel 2 that can be closed in an airtight manner, into which the material 3 to be treated, indicated by dotted line, can be filled. In the case of material to be treated one deals in particular with animal and human preparations, organs or body parts.

The vessel 2, which can have any external shape, has a door 4, through which the interior of the vessel 2 can be accessed and by means of which the vessel can be closed in an airtight manner even after charging it with the material 3 to be treated.

An air supply line 5 is connected to the vessel 2, said line being connected to at least one compressor 6. Preferably a cooling unit 7 is positioned in the air supply line 5, the cooling unit provided particularly between the compressor 6 and the vessel 2. The air drawn in by the compressor 6 via a suction line 8 is preferably first conveyed through an air filter 9.

In the air supply line 5 there is an air pressure valve 10, in particular immediately before the vessel 2.

Furthermore, an air discharge line 11 is connected to the vessel 2 in which line a discharge valve 12 is provided.

A pressure sensor 13 serves the purpose of measuring the air pressure prevailing in the vessel 2 and the temperature in the vessel can be measured with a temperature sensor 16.

The valves 10 and 12, the pressure sensor 13 and the temperature sensor 16 as well as the compressor 6 and the cooling unit 7 are connected to a control device 14, by means of which the treatment process according to the invention is automatically controlled. A particular operating program for the progress can be specified particularly via an operating field 15. By virtue of this it is possible to suit the various materials to be treated and other specifications.

After charging the vessel 2 with the material 3 to be treated and after closing the door 4 and the air discharge line 11 with the aid of the discharge valve 12 in an airtight manner, the compressor 6 is switched on via the control device 14, so that in the case illustrated air, cooled with the aid of the cooling unit 7, is conveyed via the air supply line 5 into the interior of the vessel. On this occasion the internal pressure of the vessel is built up to at least 10 bar.

When the pre-set pressure is reached, it is sensed by the pressure sensor 13 and the compressor 6 is switched off via the control device 14. In this high-pressure phase the air supply line 5 is closed with the aid of the air pressure valve 10.

After a period of time, that can also be set, the discharge valve 12 is opened by the control device 14, until the air pressure in the interior of the vessel 2 is reduced to a specifiable value that can be detected by the pressure sensor 13. This pressure, reduced in comparison with the prior prevailing high pressure, may be between atmospheric pressure and the prior prevailing high pressure, however, its reduction up to atmospheric pressure is preferred. The discharge valve 12 is subsequently closed again, the air pressure valve 10 is opened and compressed air is conveyed again by the compressor 6, until a specified pressure is reached in the vessel 2, that is again at least 10 bar. The number of periodic pressurising with reliefs of the pressure in between, can be varied depending on the material to be treated.

With the aid of the temperature sensor 16 the cooled compressed air, conveyed via the cooling unit 7, can be kept in a specified temperature range.

The temperature is preferably kept in a region around 0°C, because at this temperature a particularly good exchange of carbon dioxide and oxygen takes place inside of the material to be treated. In addition, the bacterial decomposition is minimised at this temperature.

Fig.2 shows a constructive variation of the device 1a according to the invention, wherein high-pressure reservoirs 17 are provided between the compressor 6 and the treatment vessel 2. In the embodiment two of these high-pressure reservoirs 17 are illustrated, while the number of the reservoirs may vary depending on the requirements and site conditions. Instead of several small reservoirs a corresponding larger one could be employed.

With the aid of the compressor the high-pressure reservoirs 17 are filled with compressed air, while the filling pressure may be in the range of, for example,

50-1000 bar. The filling pressure is usually approx. 300 bar, because commercially available reservoirs can be used for these pressures.

The high-pressure reservoir(s) 17 is (are) connected to the vessel 2 via a compressed air supply line 18 and the air pressure valve 10 located on the inlet side of the treatment vessel 2.

In the case of reservoirs 17 acting as intermediate vessels for the compressed air a pressure-reducing valve (not illustrated) may be provided, so that compressed air at a constant pressure that is independent, to a great extent, from the internal pressure of the reservoir can be supplied to the vessel 2via the compressed air supply line 18.

In the embodiment shown in Fig.2 the treatment container 2 is situated inside of a cooling chamber 19 to enable to keep the internal temperature of the vessel 2, for example, at approx. 4°C.

The use of high-pressure reservoirs 17 has, inter alia, that advantage that the compressor has to be operated only to fill the reservoir 17 and it does not operate while the pressure in these reservoirs is adequate.

When device 1a is started up, atmospheric pressure prevails first in the treatment vessel 2 and the material 3 to be treated is placed in these vessels 2. At this time the temperature of the ambient atmosphere within the vessel 2 is 4°C or less. When the discharge valve 12 is closed, the filling process commences, whereby the inside pressure of the vessel 2 is increased periodically with increase and decrease phases up to a specified end pressure, e.g. 20 bar.

Fig.5 is a diagram, showing the progression of the pressure inside of the vessel 2 during the filling process on the one hand, and on the other, in dotted line, the progress of the temperature of the internal atmosphere of the vessel. In this embodiment the pressure increases from the atmospheric one up to 15 bar and the temperature moves between approx. 5°C and 0°C.

Beginning with the atmospheric pressure in the vessel 2, first of all the pressure is increased in a first period, whereby the pressure increase can be 10 bar. This pressure increase also brings about an increase of the temperature in the interior of the vessel, which, however, is compensated by a subsequent decrease of the pressure by approx. 1/3 to 1/2 of the previous pressure increase, together with the cooling of the vessel 2. If the level of temperature after the decrease of the pressure and a following time span is within a permissible range, the next pressure increase takes place with a subsequent partial decrease of the pressure, in each case while observing the temperature of the vessel. Experiments have shown that despite the increased overall pressure by decreasing the pressure short-term temperatures may occur below the temperature specified for the cooling.

The periods with pressure increase and pressure decrease are repeated until the required pressure level of, for example, 15 bar, is reached. In practice this could occur after 5-10 minutes.

This operational state remains over the treatment period of the material 3 to be treated. From the diagram according to Fig.6 it can be seen that the pressure is varied periodically, whereas the temperature is kept constant at approx. 0°C.

During the treatment period a partial air exchange can be carried out, whereby some air is discharged and subsequently compressed air is supplied. This limited air exchange can be carried out at short time intervals, while at somewhat longer time intervals, for example on every hour, the air exchange can be to a greater extent. At the same time a partial, or perhaps even a complete air exchange is possible in the treatment vessel.

After the treatment period, after the removal of the material 3 to be treated from the vessel 2, the pressure is reduced, while this may last, for example, half an hour. A relatively slow reduction of the pressure takes place, so that a too quick a temperature reduction will be avoided by virtue of the pressure reduction.

Fig.7 shows the ventilation process, wherein the pressure is reduced over a period of approximately half an hour from approx. 15 bar to atmospheric pressure.

Fig.3 shows a further version of the device 1b according to the invention, wherein the treatment vessel 2 is not situated in a cooling unit, as is the case in Fig.2. For this reason a cooling equipment 7a is connected downstream to the reservoirs 17, so that cooled air could be supplied to the vessel 2 to achieve the desired temperature in the vessel.

In the case of the embodiment according to Fig.4 a compressor 6 with a filling station 20 is allocated to several treatment units 21, each having a vessel 2, an air pressure valve 10, a discharge valve 12 as well as a control device 14. The treatment units 21 can be arranged spatially separated from the compressor 6. To each treatment unit 21 at least one mobile high-pressure reservoir 17 can be connected. This high-pressure reservoir can be filled at the central filling station 20, to which the compressor 6 is connected, and then connected to the respective treatment unit. Thus only one single filling station with compressor is required, via which several treatment units 21 can be supplied.

Claims

1. A method to preserve animal and human preparations as well as microorganisms or similar material to be treated, in particular for medical research and/or training and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby carbon dioxide is expelled from the cells of the material to be treated, characterised in that the material to be treated is subjected inside a vessel to atmospheric air that is increased periodically up to at least approx. 10 bar and subsequently, after a specifiable period of time that is adjusted to suit the material to be treated, is reduced, that after the decrease of the pressure air is supplied from the outside and the pressure is increased up to at least approx. 10 bar and that at least two pressure phases are provided for a treatment.

2. A method according to claim 1, characterised in that the periodic treatment with alternating pressurising of the material to be treated is carried out with a maximum pressure in the range of approx. 10 bar up to approx. 100 bar.

3. A method according to claim 1 or 2, characterised in that the material to be treated is pressurised with high pressure on the one hand and on the other hand with a pressure reduced relative to the high one for different time spans and that the pressurising with high pressure lasts at least for approx. 1 minute per period and in particular lasts longer than the pressurising with low pressure.

4. A method according to any one of claims 1 to 3, characterised in that the pressure relief is carried out from high pressure to atmospheric pressure.

5. A method according to any one of claims 1 to 4, characterised in that the periodic pressurising for a portion of the material to be treated is carried out over a time span of a few seconds, preferably from three minutes up to twenty hours.

6. A method according to any one of claims 1 to 5, characterised in that the time span of the periodic pressurising is chosen depending from the allocated maximum pressure and/or the material to be treated.

7. A method according to any one of claims 1 to 6, characterised in that filtered and/or cooled atmospheric air is supplied to the vessel.

8. A method according to any one of claims 1 to 7, characterised in that the blood vessel system of a preparation formed by a part preparation or a complete body or an organ or body part is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like.

9. A method according to any one of claims 1 to 8, characterised in that the organ or body part to be transplanted is connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to an artificial blood circulation.

10. A method according to any one of claims 1 to 8, characterised in that after being preserved, when carrying out experiments, especially simulating surgical operations, the blood vessel system of a preparation, formed by a part preparation or a complete body preparation, is connected to a through-flushing by fluid, in particular to an artificial blood circulation and that for this purpose the preparation or the similar material to be treated with at least one large blood vessel is connected to a preferably pulsating fluid supply, in particular with at least one large artery and/or at least one vein.

11. A method according to claim 8 or 10, characterised in that the blood circulations of the preparation or the like are filled with a blood substitute that has a colloid-osmotic pressure that is comparable with that of blood.

12. A method according to claim 11, characterised in that the blood substitute or similar fluid is filled into the blood stream of the preparation by means of a pressure pump connected to at least one blood vessel.

13. A method according to any one of claims 1 to 12, characterised in that the atmospheric air is compressed and then is supplied to the vessel (2) filtered and/or cooled.

14. A method according to any one of claims 1 to 12, characterised in that the atmospheric pressure is compressed, stored intermediately at a pressure of between approx. 10 bar and approx. 1000 bar and then supplied to the vessel (2), preferably filtered and/or cooled.

15. A method according to any one of claims 1 to 14, characterised in that the treatment of the material to be treated is carried out in a cooled ambient atmosphere approx. between -2°C and +5°C.

16. A method according to any one of claims 1 to 15, characterised in that the vessel (2) for the material to be treated is cooled preferably by a cooled ambient atmosphere and that the time spans with a periodic pressure increase and a subsequent pressure decrease in the vessel (2) are so determined that at the end of each time span a specifiable temperature will prevail in the vessel (2).

17. A device to preserve animal and human preparations as well as microorganisms or similar material to be treated and to prolong the viability of organs and body parts to be transplanted which serve as material to be treated, whereby the device has at least one vessel that can be closed in an airtight manner to accommodate the material to be treated, with a gas supply line as well as a gas discharge line connected to said vessel, to carry out the method according to any one of claims 1 to 16, characterised in that a compressor (6) is connected to the gas supply line (5) to supply ambient air to the vessel (2), that a discharge valve (12) is provided in the gas discharge line (11), that a pressure sensor (13) is provided to measure the internal pressure of the vessel and that the compressor (6), the discharge valve as well as the pressure sensor (13) are connected to a control device (14) for the purpose of a periodic supply and discharge of the air.

18. A device according to claim 17, characterised in that in the gas or air supply line (5), in particular after the compressor (6), a filter (9) and/or a cooling equipment (7) is provided.

19. A device according to any one of claims 17 to 18, characterised in that as the source of the compressed air at least one high-pressure reservoir (17) is provided for an operating pressure of approx. 10 bar up to 1000 bar.

20. A device according to claim 19, characterised in that the high-pressure reservoir (17) is connected or can be connected to the compressor (6) and on the other hand it is connected to the treatment vessel (2) via air pressure valve (10).

21. A device according to any one of claims 19 to 20, characterised in that the treatment vessel (2) is connected with a cooling equipment and is arranged preferably in a cooled ambient atmosphere, in particular in a cooling chamber (19).

22. A device according to claim 21, characterised in that the treatment vessel (2) is provided with a cooling jacket as a cooling equipment.

23. A device according to any one of claims 19 to 22, characterised in that the high-pressure reservoir (17) is arranged in a cooled ambient atmosphere, in particular in a cooling chamber (17).

Abstract

A device to preserve animal and human preparations as well as microorganisms or similar material (3) to be treated, in particular for medical research and/or training. In addition to prolong the viability of organs and body parts to be transplanted which serve as material to be treated (3). For both fields of application carbon dioxide is expelled from the cells of the material to be treated.

The device has a vessel (2) that can be closed in an airtight manner to accommodate the material to be treated, to which a gas supply line (5) and a gas discharge line (11) are connected. A compressor (6) is connected to the gas supply line (5) to supply ambient air to the vessel (2) and the compressed air can be discharged from the vessel (2) via a discharge valve (12) in the gas discharge line (11).

The material (3) to be treated is exposed inside the vessel (2) to atmospheric air with periodically increasing pressure up to at least approx. 10 bar and subsequently, after a specifiable period of time, to a reduced pressure. After reducing the pressure, air from the outside is supplied by the compressor (6) and the pressure is increased again up to at least approx. 10 bar. At least two pressure phases are provided for a treatment. The treatment method is automatically controlled by means of a control device (14).

(Fig.1)

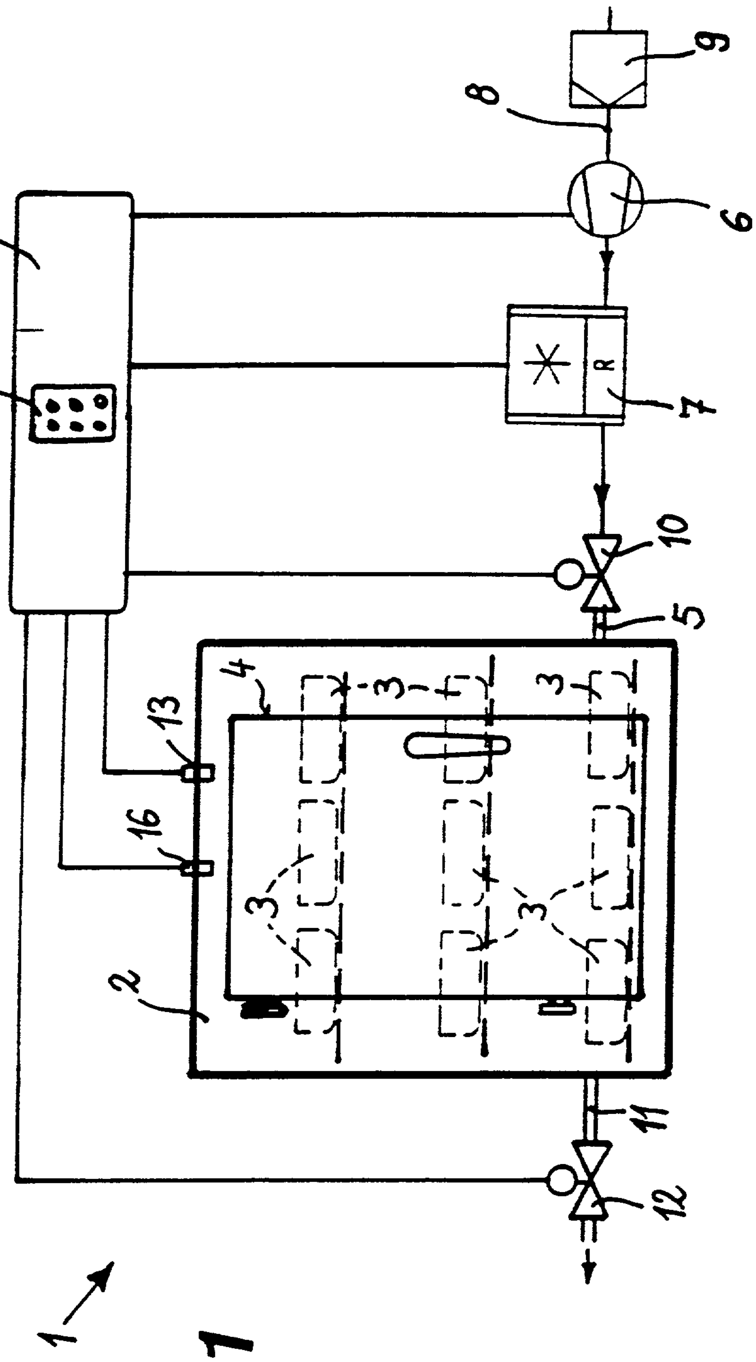

Fig.1

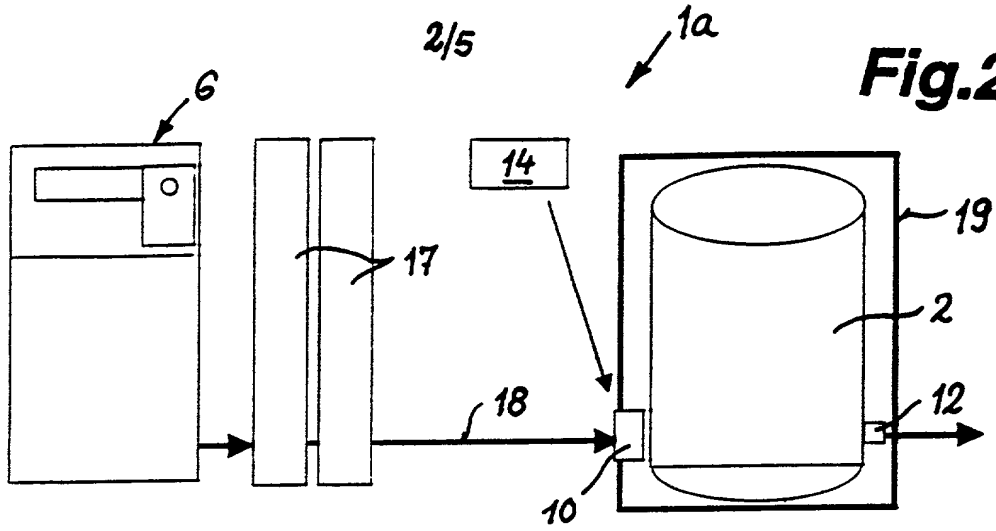

Fig.2

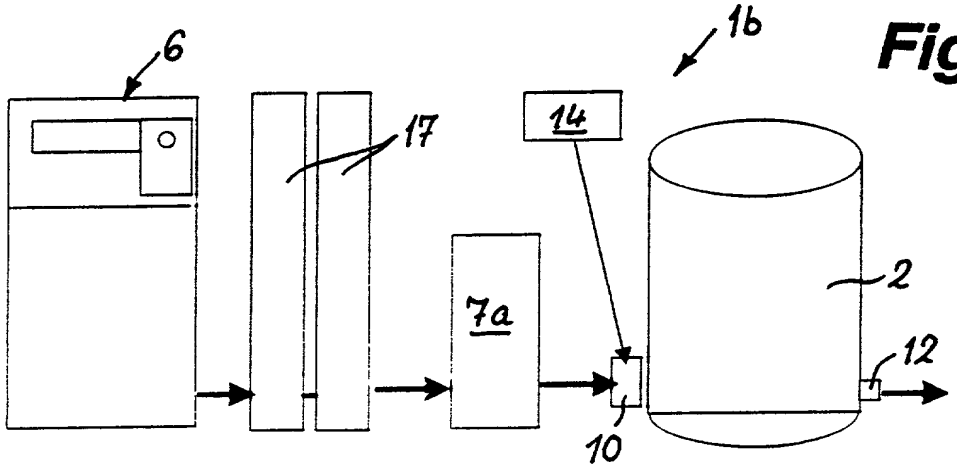

Fig.3

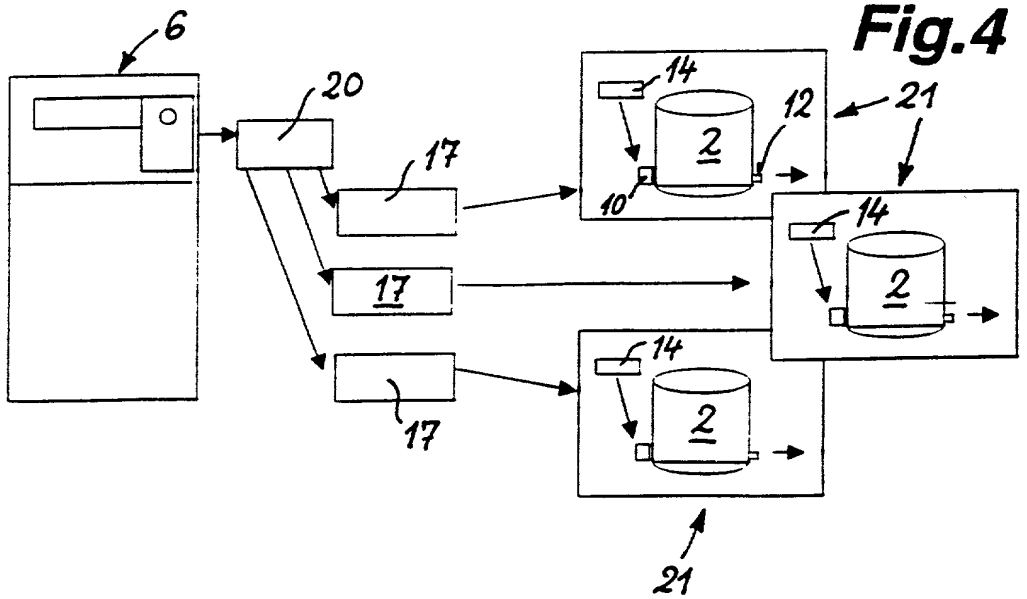

Fig.4

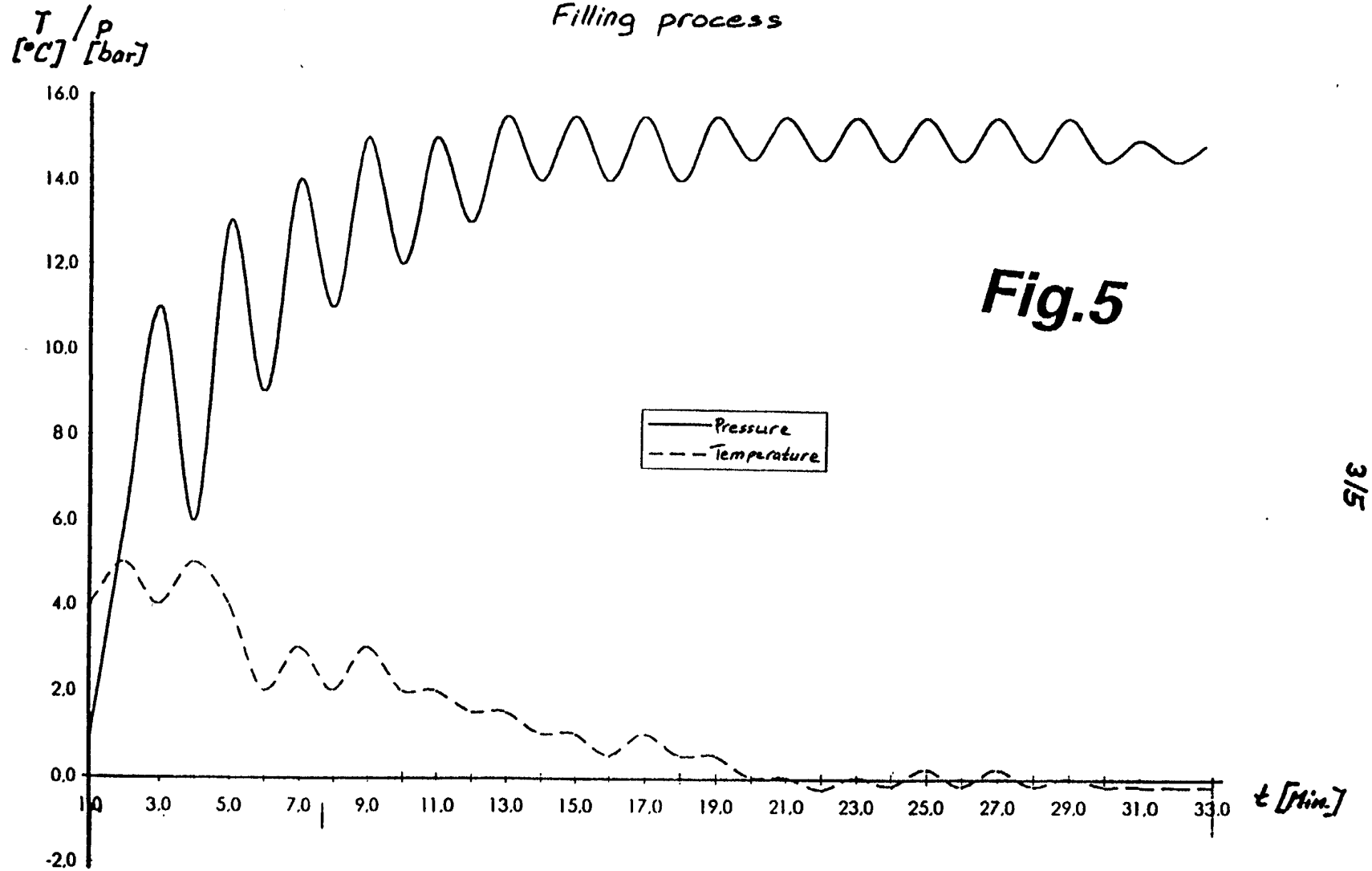

Fig.5

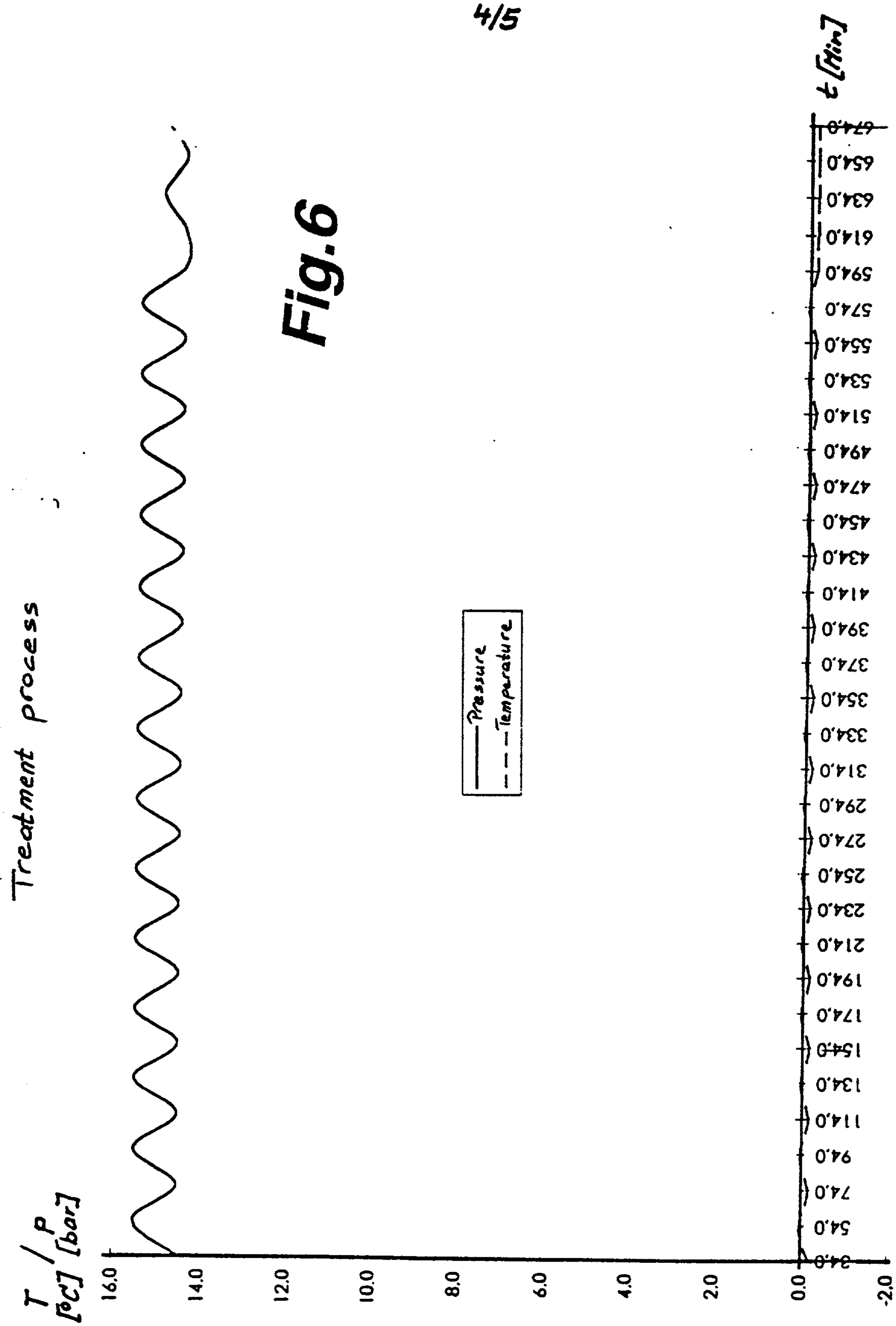
Treatment process
T [°C] / P [bar]
t [Min]
Pressure
Temperature
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
-2.0
34.0
54.0
74.0
94.0
114.0
134.0
154.0
174.0
194.0
214.0
234.0
254.0
274.0
294.0
314.0
334.0
354.0
374.0
394.0
414.0
434.0
454.0
474.0
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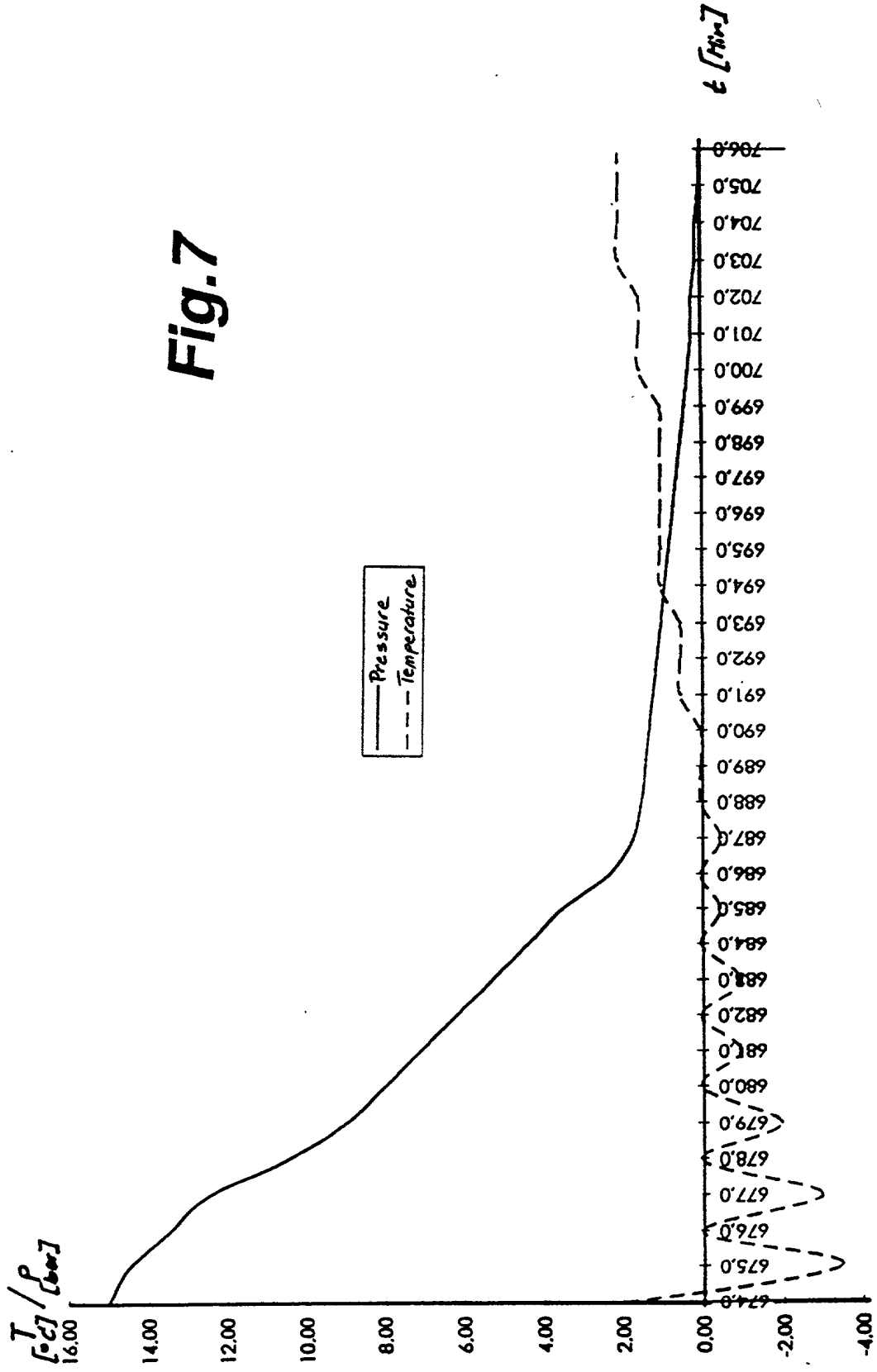
Fig.6

Fig.7



10 MAY 2002

10/030805

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	SMB-PT038 (PC 00 430 B US)
First Named Inventor	Klemm et al.
COMPLETE IF KNOWN	
Application Number	10/030,805
Filing Date	Not Yet Known
Group Art Unit	Not Yet Known
Examiner Name	January 11, 2002

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND DEVICE FOR PRESERVING ANIMAL AND HUMAN PREPARATIONS AS WELL AS MICROORGANISMS AND FOR PROLONGING THE VIABILITY OF ORGANS AND BODY PARTS TO BE TRANSPLANTED

(Title of the Invention)

the specification of which
☐ is attached hereto
OR
☒ was filed on (MM/DD/YYYY) 07/7/2000 as United States Application Number or PCT International Application Number PCT/EP00/06430 and was amended on (MM/DD/YYYY) _____ *(if applicable)*.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
199 32 375.5	Germany	07/13/1999	☐	☐	☒
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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Filing Date	Not Yet Known
Group Art Unit	Not Yet Known
Examiner Name	January 11, 2002

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND DEVICE FOR PRESERVING ANIMAL AND HUMAN PREPARATIONS AS WELL AS MICROORGANISMS AND FOR PROLONGING THE VIABILITY OF ORGANS AND BODY PARTS TO BE TRANSPLANTED

(Title of the Invention)

the specification of which
☐ is attached hereto
OR
☒ was filed on (MM/DD/YYYY) 07/7/2000 as United States Application Number or PCT International Application Number PCT/EP00/06430 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
199 32 375.5	Germany	07/13/1999	☐	☐	☒
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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Please type a plus sign (+) inside this box → [+]

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/EP00/06430	07/07/2000	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☒ Customer Number 3624 → *Place Customer Number Bar Code Label here*
OR
☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Namely, the Attorneys of Volpe and Koenig, P.C.			

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 3624 *OR* ☐ Correspondence address below

Name	VOLPE AND KOENIG, P.C.				
Address					
Address					
City		State		ZIP	
Country		Telephone		Fax	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Bernd	Klemm

Inventor's Signature						Date	
Residence: City	Kaiserslautern	State		Country	Germany	Citizenship	Germany
Post Office Address	Auf dem Bannjerruck 3						
Post Office Address							
City	Kaiserslautern	State		ZIP	D-67663	Country	Germany

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/EP00/06430	07/07/2000	

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OR

☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Namely, the Attorneys of Volpe and Koenig, P.C.			

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 3624 *OR* ☐ Correspondence address below

Name	VOLPE AND KOENIG, P.C.				
Address					
Address					
City		State		ZIP	
Country		Telephone		Fax	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Bernd	Klemm

Inventor's Signature	X					Date	2 Apr 2002
Residence: City	Kaiserslautern	State		Country	Germany	Citizenship	Germany
Post Office Address	Auf dem Bannjerruck 3						
Post Office Address							
City	Kaiserslautern	State		ZIP	D-67663	Country	Germany

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 1

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
Andreas	Melzer
Inventor's Signature X Andreas Melzer	**Date** X 28.03.2002
Residence: City Mulheim a.d. Ruhr	**State** **Country** Germany **Citizenship** Germany
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City Mulheim a.d. Ruhr	**State** **ZIP** D-45478 **Country** Germany

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
Jurgen	Schlegel
Inventor's Signature	**Date**
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
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Mailing Address	
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City	**State** **ZIP** **Country**

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Given Name (first and middle [if any])	Family Name or Surname
Andreas	Melzer
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City Mulheim a.d. Ruhr / **State** / **ZIP** D-45478	**Country** Germany

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
Jurgen	Schlegel
Inventor's Signature	**Date** 3.4.02
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Mailing Address Hauptstrasse 9 DEX	
Mailing Address	
City Umkirch / **State** / **ZIP** D-79224	**Country** Germany

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
Inventor's Signature	**Date** 3.4.02
Residence: City / **State** / **Country**	**Citizenship**
Mailing Address	
Mailing Address	
City / **State** / **ZIP**	**Country**

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